

**EPA Response**  
**CPG’s September 2015 Response to EPA Comments Submitted May 1, 2015 (CPG RTC)**  
**Draft Lower Passaic River Study Area Baseline Ecological Risk Assessment Submitted June 13, 2014**  
**by the Lower Passaic River Study Area Cooperating Parties Group**

**General Comments**

No.	EPA General Comment Submitted 5/1/2015	CPG RTC Submitted 9/10/2015 or 9/15/2015	EPA Response to CPG RTC
1	<p>Calculated Hazard Quotients for all media must be clearly presented and discussed in the document, both in detail in the relevant sections and in summary form elsewhere in the document (for example, in the Executive Summary). All EPCs must be presented, and compared to their respective TRVs and resulting HQs. Most notably, the main text of the document does not include a table or even a detailed discussion of sediment EPCs as was presented for other media, even though sediment most likely represents the primary pathway for exposure of ecological receptors to site-related chemicals.</p> <p>The document should be prepared in such a way that determining the overall characterization of risk through all media is straightforward, clear and transparent. Please review the entire document and revise accordingly.</p>	<p>The CPG disagrees with Region 2’s contention that the BERA lacks clarity and transparency; the characterization of risk to ecological receptors located within the 17-mi LPRSA is clearly and concisely presented.</p> <p>To aid Region 2’s review, in the revised BERA, text will be added to point the reader to the analysis conducted in the SLERA and the findings will be summarized in the BERA.</p> <p>It should be noted that sediment EPCs are compared to their respective media-specific TRVs (NJDEP ESLs) in the SLERA (see comprehensive tables in Appendix A, Attachment A2) and were not repeated in the main text of the BERA to save repeating analysis covered elsewhere in the document and for practical purposes of presentation due to the large number of chemicals evaluated. It should be noted that over 1,800 cells are populated in Attachment A2 tables comparing sediment EPCs to SLs.</p>	<p>EPA will evaluate the CPG’s additions to see if they add the necessary clarity when the revised document is submitted.</p> <p>The additions should include changes to tables. For example, a table showing HQs should also show the EPCs and TRVs used to derive the HQs. It should not be necessary to go to multiple tables, wherever they may be, to see the EPC, TRV, and resulting HQ. At least for the major COPECs, Risk Characterization should reveal EPCs, TRVs and HQs for those most important chemicals, and this presentation/summary should be complete to facilitate evaluation of results.</p>
2	<p>For the majority of receptors and exposure pathways, the draft BERA evaluates the river as a single exposure unit by combining all of the data into one exposure point concentration (EPC). In order to fully characterize ecological risks, EPCs must also be developed to evaluate smaller areas. For each receptor and/or exposure pathway, EPCs and their associated risk estimates should be provided for individual mudflats, increments based upon river mile and increments based upon zone (e.g., estuarine, transition, freshwater).</p>	<p>Region 2’s comment is factually incorrect and is not supported by the information provided in the entire draft BERA.</p> <p>The draft BERA includes exposure areas identified by receptor based on ecological relevance. Mammalian receptors, such as mink, were evaluated only a portion of the LPRSA (&gt; RM 10) that is ecologically relevant, not the entire LPRSA (see Section 9.1.2 of the BERA). A less than Site-wide exposure (i.e., &gt; RM 10) was also conducted for river otter as part of the uncertainty discussion (see Section 9.1.4.2 and Table 9-15 in the BERA). In addition, exposure units for the spotted sandpiper included a smaller-scale analysis based only on mudflats within a 2-mi reach range (see Table 8-14 of the draft BERA), consistent with the home ranges of breeding pairs. The Region 2-approved QAPPs were not designed to evaluate areas as small as single mudflats, so an analysis at this level of detail will result in evaluations based on maximum concentrations (where data are available), which will result in an outcome already presented in the SLERA.</p> <p>Arbitrarily dividing up the river is not sound science and is inconsistent with the technical direction given by Region 2 previously. The exposure areas presented in the draft BERA were discussed with Region 2 through meeting presentations (March 6, 2014) and are discussed in the RARC Plan (Windward and AECOM 2013) (see pages 34 and 46–47 and Table 2-2). As stated in the RARC Plan, exposure areas were based on the results of site-specific surveys, literature reviews, development of the life history profiles for each receptor, and site-specific habitat characteristics and chemical characterization. Based on discussions with Region 2, it was agreed that ecologically relevant exposure areas would be identified.</p> <p>Further, the comment directs CPG to take an approach that is inconsistent with the ecological risk assessment presented in Region 2’s 8-Mile FFS RI (Louis Berger et al. 2014) (see Appendix D, Section 4.2.1, paragraph 1). This comment also conflicts with Region 2’s January 2013 comment No. 107 on the Newark Bay Problem Formulation Document exposure areas: “Habitat, rather than geomorphic and geographic areas, is a much better way to describe the exposure areas for ecological receptors, and should be referenced here.”</p> <p>At Region 2’s request (per discussion with Region 2 during the May 21, 2015, teleconference), CPG has provided a table (attached; Table 1) of the proposed exposure areas per receptor as well as which exposure areas were already evaluated in the draft BERA. Smaller than site-wide exposures are included for all bird and mammal receptors as part of either the risk characterization or the uncertainty evaluation for the revised BERA. As CPG does not agree that smaller non-ecologically relevant exposure areas are relevant and appropriate, and will lead to inaccurate estimates of risk, the text of the revised BERA will reflect the uncertainties and limitations of this approach.</p>	<p>As discussed during several meetings leading up to the submission of the BERA, EPA has asked for an evaluation of multiple exposure points to provide the reader and risk manager with a clear understanding of the nature and extent of contamination and the potential for exposure in different areas of the river. EPA is not discounting the use of current exposure point concentrations. EPA is requiring additional exposure point concentrations be provided to better characterize the risk posed by smaller areas within the river, as was done for the sandpiper and mudflats. Table 1, which was attached to the CPG’s response to comments, does not address the approach required by EPA. EPA has revised this table to reflect expectations for the next version of the document. Pink rows in the table provided by the CPG should have calculations provided. The rationale provided in the tables for not including these calculations would be the basis for the discussion in the uncertainty of these calculations. In addition to the receptors listed in the table, risk estimates by reach, or smaller areas when data allows, should be included for all receptor groups.</p> <p>As is noted in EPA’s 6/19/2015 letter to the CPG, the approach directed by EPA is not inconsistent with the Focused Feasibility Study (FFS). The FFS evaluated only two exposure points: the full lower 8 miles and mudflats. This decision was based on the finding that median surface sediment concentrations do not change significantly within the lower 8 miles. However, this is not the case above River Mile (RM) 8.3. As such, evaluating the river as a single exposure unit for the majority of receptors and exposure pathways is not appropriate for the full 17-mile LPRSA. Additionally, this approach is consistent with the October 2013 Draft Risk Analysis and Risk Characterization Plan (RARC).</p>

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3	<p>The draft BERA appears to eliminate evaluations of chemical contamination in common carp, a benthic omnivorous fish. Benthic omnivorous fish are instead represented by mummichog and banded killifish/darters. As stated in the summary of the Problem Formulation in the Executive Summary of the draft BERA, risks are to be evaluated using species representing specific trophic levels or feeding guilds.</p> <p>Refer to the following text excerpted from the Executive Summary on page ES-10:</p> <p>“In the problem formulation, focal species or representative species per feeding guild are selected for evaluation of that particular feeding guild. For example, the spotted sandpiper was selected to represent probing invertivorous birds that may forage in the LPRSA.”</p> <p>The draft BERA notes that a wide variety of aquatic species were collected and analyzed for contaminants. These include American eel, blue crab, brown bullhead, carp, channel catfish, largemouth bass, northern pike, smallmouth bass, white catfish, white perch, white sucker, and SFF (i.e., gizzard shad, mixed forage fish, mummichog, pumpkinseed, silver shiner, spottail shiner, and white perch). Despite this large dataset, the draft BERA limits discussion of contaminants in fish tissue to only a subset of these taxa, and there is little or no discussion of contaminant concentrations measured in several of the taxa collected. Examples of fish for which tissue data are available yet not evaluated are carp and multiple ictalurids, none of which are discussed in the draft BERA. Table 4-3 indicates that evaluation of carp and white sucker tissue data is limited to the uncertainty section. Elimination of chemical data for these species’ tissue results in the elimination of representatives of a group of receptors.</p> <p>All available biota tissue data need to be evaluated in the risk characterization section of the BERA.</p>	<p>All fish tissue data, representing more than 10 species (i.e., mummichog and other forage fish species, white perch, channel catfish, brown bullhead, white catfish, white sucker, American eel, largemouth bass, smallmouth bass, and northern pike), were evaluated in the fish risk assessment of the BERA (some are included in the uncertainty evaluation), with the exception of carp. Carp were not listed in the Region 2-approved PFD, nor in the draft RARC Plan, as a species of interest, because carp are an invasive species and not a species to be protected. Moreover, Region 2 directed the CPG to analyze only large carp, the rationale being that these could potentially be consumed by humans. Carp eradication programs are being implemented around the country due to the destructive behavior of the species (see BERA Appendix N for details of environmental impacts of carp). Carp that were caught during the 2009 fish sampling program were kept at the direction of Region 2, per the June 30, 2009, call. As documented in the Fish/Decapod Tissue QAPP (Windward 2009a), it was agreed during this call that carp were not a target species. Mummichog and banded killifish/darters were identified in the Region 2-approved PFD as the focal species to represent omnivorous fish and were correctly presented as such in the BERA.</p> <p>The statement that “the draft BERA limits discussion of contaminants in fish tissue to only a subset of these taxa” is therefore a gross and inaccurate mischaracterization of the material presented in the BERA. In fact, all of the tissue data for all of the species listed by the reviewer, with the exception of carp, were presented and discussed in the BERA (for example, see Table 7-9 for the evaluation of non-target fish).</p> <p>Region 2’s comment directs CPG to take an approach inconsistent with previous agreements and documentation from Region 2; see PFD Table 5-1 (Windward and AECOM 2009). The PFD went through multiple rounds of review by Region 2 and was approved on July 31, 2009. The proposed use of carp based on the size of carp collected in the LPRSA as potential prey for heron and kingfisher has no scientific justification. Common carp caught from the LPRSA and analyzed were nearly double (or more) the maximum lengths of fish reported as great blue heron and belted kingfisher prey (see Table 2 and Figure 1, attached separately). Note that none of the BERAs cited by Region 2 (Fox River, Tittabawassee River, Portland Harbor, and Kalamazoo River) used carp as a prey for smaller birds (heron or kingfisher).</p> <p>The pictures provided by Region 2 in May 2015 show that heron could eat fish approximating their beak size, which can be supported by including a scenario with fish up to 30 cm in length (~12 in.) for heron and 18 cm in length (~7 in.) for kingfisher. While carp within this size range may be consumed by heron and kingfisher, the carp analyzed from the LPRSA at the direction of Region 2 are significantly larger (ranging from approximately 55 to 60 cm; see Figure 1 [attached]) and are unrealistic prey for these bird receptors. Moreover, the concentrations in these extremely large carp are not representative of exposure concentrations in smaller carp due to the larger body size, as well as the longer exposure time of larger carp (carp can live up to 9 to 15 years in the wild (Werner 2004)).</p> <p>At Region 2’s direction, carp will be added as a portion of mink and river otter diet in the uncertainty analysis, although the literature supports that these larger fish (&gt; 30 but &lt; 70 cm in length) would be a small fraction of their diet.</p> <p>In summary, in the revised BERA, carp will not be evaluated for protection of carp, and the benthic omnivore feeding guild already has a representative fish per earlier agreements with EPA (see PFD Table 5-1). Carp and other large fish (&gt; 30 cm) will be evaluated as part of the uncertainty assessment as possible prey in the mammalian diet per direction from Region 2. Carp will not be fed to the avian receptors since it is not ecologically relevant, although the evaluation of medium-sized fish (see Table 2, attached) will be evaluated as part of the uncertainty assessment as possible prey in heron and kingfisher diets.</p>	<p>The memorandum “Revised Sample Analysis Plan for Catfish/Bullhead, Carp, Bass, White Sucker, and Northern Pike Tissue for the Lower Passaic River Restoration Project (Revised Fish Sample Analysis Plan, Part 1)” dated May 21, 2010 specifically indicates that carp will be evaluated in the BERA and identifies that carp were included as an alternate species. The CPG must make the changes as directed by EPA regarding evaluating carp in the BERA.</p> <p>As stated in EPA’s 6/19/2015 letter, a significant number of carp were collected from the LPRSA, and an adequate number were collected for tissue analysis and evaluation in all but two reaches of the river. This is the most complete tissue data set that is available for freshwater fish. As such, carp should be evaluated in the BERA so that one representative species can be evaluated for the majority of the river, which aids in understanding potential risks to other omnivorous benthic fish that were not captured in specific sections of the river. In addition, carp are consumed by other fish and terrestrial predators, such as the Great Blue Heron. The CPG argues that carp should not be protected, but this is not what EPA is asking for. Carp represent a specific and important group of fish with similar characteristics and life histories (large, long-lived, fatty, benthic, omnivores).</p>

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4	<p>Stated low risks to benthic communities appear to be linked to assumptions that only the upper few centimeters (often stated as including only the upper 1-2 cm) of sediment are inhabited or used by benthic macroinvertebrates (BMI). This assumption is not supported by observations or the literature, which clearly identify deeper sediments often stated to be at least the upper 15 cm, and possibly including depths of several feet for some polychaetes and oligochaetes as habitat to BMI. The draft BERA states in numerous locations that the biologically active zone is 0 to 15 cm, while concluding that BMI are limited to or nearly limited to the upper 2 cm of surface sediments.</p> <p>There is also inconsistency in how the draft BERA defines surface sediment – in some instances it is defined as the biologically active zone and in others as the depth of sediments used by BMI.</p> <p>Throughout the BERA the following statement is presented:</p> <p>“The chemical signatures in sediment from this shallow biologically active zone (the 0-to-2-cm depth interval) may differ from the chemical signatures of deeper sediments collected from the LPRSA (from 0 to 15 cm).”</p> <p>It is unclear what the point of the above statement may be regarding the BMI community habitat. What we do know is that there is insufficient data to determine whether there are significant differences between the depths or the directionality of any differences. Based on the very small number of high resolution coring results available, the shallower depth horizon may have lower or higher concentrations.</p> <p>The entire document must be revised to resolve these inconsistencies and address these issues.</p>	<p>Region 2’s comment is totally unsupported in the text of the BERA; Region 2 is well aware that the CPG utilized the full 0- to 15-cm sediment concentrations to develop sediment EPCs for benthic invertebrates. The evaluation of risk was based on the WOE from data collected over the upper 15 cm of sediment, not the 0- to 2-cm horizon. Any discussion of BMI being primarily present and feeding within the upper 2 to 5 cm is well supported by the literature in terms of measured biomass across field study benthic community surveys conducted as part of the 17-mi LPRSA. Stated low risks are a clear extension of the level of impacts associated with urban conditions, as evidenced by the similarity between LPRSA benthic samples and those from Jamaica Bay or above Dundee Dam.</p> <p>Nonetheless, the CPG will ensure that it is clearly understood by Region 2 in revised 17-mi BERA that the surface sediment EPCs are based on the upper 15-cm sediment depth.</p>	<p>If the sediment EPCs for BMI are based on the 0-15 cm depth interval, then the proposed revision will be adequate. However, the text should be consistent and reference to the upper 2 cm as the biologically active zone should be eliminated or revised.</p> <p>The CPG has invoked dispute resolution over this topic and, as such, it is being discussed further outside of the context of the BERA.</p>
5	<p>There is a large gap between TRVs/CBRs that are supported by EPA and TRVs/CBRs that are supported by the CPG. Many of the TRVs EPA has recommended for use have been discarded with a bias towards minimizing risk. For example, there is much discussion throughout the draft BERA of the low magnitude of HQs (generally below 2), yet those same low HQs are often based on selection of higher (and less appropriate) TRVs. For example, the HQ would be considerably higher if an alternate (and more appropriate) TRV were used to derive the HQ for total PCBs in fish eggs.</p> <p>The risk characterization sections must use appropriately conservative TRVs, including values referenced throughout these comments. EPA will accept the presentation of multiple TRVs/CBRs for individual compounds in the BERA to provide upper- and lower-bounds of risk estimates.</p>	<p>Region 2 received the CPG’s TRV document in August 2011, and the CPG provided a detailed evaluation of its selected TRVs in Attachment A3 of the BERA. CPG also provided a critical evaluation of Region 2’s 2007 FFS TRVs as an attachment to the BERA (Attachment A3-1), and of Region 2’s 2014 FFS TRVs in Appendix D.1 of CPG’s comments to the 2014 FFS. However, Region 2 has not previously raised any issues regarding CPG’s TRVs or responded to CPG’s critique of its recommended TRVs. Region 2 decided to defer reviewing CPG’s TRVs at that time, delaying its criticism until May 2015. More concerning, some of Region 2’s TRVs do not meet its own scientific criteria to be included for an ecological risk assessment (see Appendix A, Supplement A-3 of the June 2014 BERA and Appendix D.1 of CPG’s comments to the 2014 FFS for CPG’s evaluation of the FFS TRVs). CPG’s critique of Region 2’s TRVs has also been recompiled and summarized in the attached Table 3. Only the few TRVs provided by Region 2 that are found to be technically valid and that meet the scientific criteria presented in the RARC and BERA will be used in the SLERA.</p>	<p>As has been discussed, the most conservative TRVs must be used in the SLERA. The CPG must also include the TRVs used in the FFS and those recommended in EPA’s comments on the BERA, and the CPG may also include what they feel are more appropriate values, which would be presented alongside the other values to bound the results.</p> <p>The response states in the attached Table 3 that EPA guidance suggests that the CBR approach for metals “does not appear to be a robust indicator of toxic dose.” This does not mean that the approach is not valid. Rather, as stated in the quoted EPA guidance, it means that the issue is complex.</p>

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6	<p>The methodology used to evaluate whether individual data points should be used for background and reference comparisons needs to be modified. The metrics approach developed by EPA and presented to the CPG in May 2014 should first be conducted, followed by an appropriate outlier analysis. For example, the outlier analysis presented in the draft BERA used an interquartile range and 3x to determine if a result was an outlier. A value of 1.5x would be more appropriate.</p> <p>EPA will provide a specific set of samples that should be used for either background or reference. In addition, EPA will provide specific details on how to incorporate this information into the document. This information will be provided within the next few weeks.</p>	<p>The CPG disagrees with this comment; the use of 1.5 x IQR unnecessarily removes results reflective of the natural variability associated with reference conditions.</p> <p>CPG conducted an outlier analysis, which was consistent with Region 2’s direction of background/reference as provided to CPG on June 28, 2013 (included as Attachment B-1 of the RARC Plan [Windward and AECOM 2013]). CPG identified the specific use of an interquartile range and 3x to determine outliers in Appendix B of the RARC Plan (Windward and AECOM 2013). EPA did not provide any comments on this specified outlier approach in its January 2014 comments on the RARC Plan.</p> <p>The use of 3x the interquartile range (3xIQR) is an appropriate screen for outliers. It is consistent with the approach laid out in the RARC Plan, which identified use of an interquartile range and 3x to determine outliers in Appendix B (Windward and AECOM 2013). Region 2 did not provide any comments on this specified outlier approach in its January 2014 comments on the RARC Plan. Further, a threshold of 1.5xIQR unnecessarily removes results reflective of the natural variability associated with background conditions.</p> <p>The CPG also notes that the guidance (Section 2.3.3 or Box 2-13 of EPA’s 2006 QA/G9) cited by Region 2 identifies 1.5xIQR as an example for identifying potential outliers. Moreover, EPA’s 2009 guidance (EPA 530/R-09-007) states in Section 9.2:</p> <p>“Potential outliers are categorized into two groups:</p> <ul style="list-style-type: none"> <li>• Data points between 1.5 and 3 times the IQR above the 75th percentile or between 1.5 and 3 times the IQR below the 25th percentile, and</li> <li>• Data points that exceed 3 times the IQR above the 75th percentile or exceed 3 times the IQR below the 25th percentile.”</li> </ul> <p>Section 9.2 also includes an example (9-2) that clearly states to:</p> <ul style="list-style-type: none"> <li>• Identify potential outliers between 1.5xIQR and 3xIQR beyond the box.</li> <li>• Identify potential outliers exceeding 3xIQR beyond the box.</li> </ul> <p>It is commonly understood in the statistical literature (Dawson 2011) that 1.5xIQR and 3xIQR provide lower and upper thresholds for potential outliers, with mild or near outliers identified as data points that fall between 1.5x and 3xIQR, and extreme outliers identified as data points in excess of 3xIQR. EPA’s 2009 guidance is consistent with the literature regarding the identification of outliers</p> <p>The example box of EPA QA/G9, which identifies a multiplier of 1.5 as the sole criterion for outlier identification, is, at best, incomplete and possibly incorrect. The use of 3xIQR is consistent with both EPA guidance and statistical literature.</p> <p>As such, the CPG will retain the 3xIQR in its analysis of background data to identify extreme outliers. As an additional analysis, potential near or mild outliers will also be identified using 1.5xIQR to evaluate the sensitivity of the background datasets to this threshold.</p> <p>Region 2 provided a Reference and SQT Methodology attachment as an addition to these comments on June 19, 2015. See above text for response to the IQR outlier. For reference datasets, the methodology provided is inconsistent with Region 2 textual definitions and purpose for establishing reference conditions. The use of a screening step for reference sediment toxicity is inappropriate, when part of the purpose of developing the dataset is to establish a toxicity threshold associated with regional conditions to be used in risk characterization. The data should represent a regional signature for chemistry and toxicity, rather than being subjected to an intensive data censoring process. In addition, the minimum concentration (after removing outlier data) was used by Region 2 for evaluating risks in Gowanus Canal; however, Region 2 now requires the CPG to use the 5<sup>th</sup> percentile of the reference data, even after subjecting the data to an onerous data-censoring procedure. For the SQT methodology, Region 2’s emphasis on placing a higher weight on the chemistry LOE is not consistent with the underlying science and site-specific conditions.</p>	<p>Based on additional discussions with the CPG, EPA is providing a revised approach to be followed for identifying outliers. This approach no longer uses an outlier analysis requiring the use of interquartile range (IQR). The attached spreadsheet provides the CPG with instructions on the application of the EPA approach and identifies the appropriate data points that should be used for reference comparison. See attachment titled <i>Mean Probable Effect Concentration Quotient (mPECq)</i>, dated October 27, 2015 (file name: TM_mPECq_102715.doc).</p>

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7	<p>The draft BERA minimizes the discussion of, and in some cases fails to recognize, observed or predicted impairment or toxicity without reference to background or reference areas. While consideration of local background or reference area data is appropriate at some point in the risk assessment, especially for risk management decision-making, it is also appropriate to present and discuss risk based on site data compared to effects data (e.g., 95% UCLs for contaminant concentrations in surface water or sediment compared to TRVs, chronic NRWQC, TECs, or PECs). This is especially critical where selected locations representing local background or reference conditions are known or expected to be contaminated (i.e., both site and background are impaired, but background less so).</p> <p>The BERA must discuss the implication of elevated risk estimates without comparison to background. The current text appears to minimize risk estimates for the site by consistently including background or reference data, leading to the conclusion of little or no risk simply because risk estimates for the site are below background.</p> <p>Please review the entire document and revise accordingly.</p>	<p>The CPG strongly disagrees with Region 2's contention there is any minimization and/or failure to adequately recognize impairment or toxicity. The risk characterization provides the calculated risks according to EPA guidance, and site-specific risk estimates are discussed within the context of the site-specific studies. All risk estimates are provided in the BERA, either in the main text or, due to the size of the tables, in the appendices. Background and reference conditions are taken into account and also provided, consistent with the previous conversations with Region 2, as documented in the RARC background appendix. Each sample result is provided in the BERA. Note that the SLERA also provides sample results compared to chemistry thresholds. In the BERA, the multiple lines of evidence are presented and then interpreted in the weight-of-evidence approach to provide risk estimates and risk conclusions. For Region 2's benefit, the CPG will review the document to enhance its transparency and make edits as necessary.</p>	<p>The revised document will be reviewed to confirm that EPA's comment has been addressed appropriately.</p>
8	<p>Numerous locations in the draft BERA appear to minimize calculated risks because it is assumed that elevated HQs are likely associated with impacts to individual organisms, but not to populations. In fact, HQs based on survival, growth or reproduction endpoints can and should be assumed to have the potential to affect not just individuals, but local populations as well. It is a common and accepted practice to extrapolate toxicity test results and similar types of data to populations and communities.</p> <p>Please revise the document accordingly.</p>	<p>The CPG strongly disagrees with Region 2's contention that there is any minimization of risk estimates. The risk characterization provides the calculated risks according to EPA guidance, and site-specific risk estimates are discussed within the context of the site-specific studies.</p> <p>Based on the May and June 2015 teleconference calls with Region 2, it appears that Region 2 has misinterpreted how risk estimates are presented. The revised BERA will summarize the risk estimates to ensure that readers can more easily follow the risk characterization process. It should be noted, however, that due to the number of receptors and chemicals, it will be necessary to summarize some of the data in appendices.</p>	<p>The revised document will be reviewed to confirm that EPA's comment has been addressed appropriately.</p>
9	<p>In many places (Section 2.1 is a good example), the draft BERA includes an extensive discussion of the stressors that are known or expected to be influencing the conditions to which ecological receptors may be exposed. These are stated to include poor quality habitat (physical conditions), channelization, weather, invasive species and discharges from CSOs and other point sources related to stormwater. These discussions are not appropriately balanced because chemical contamination from past or current industrial sources is minimized relative to physical conditions and stormwater inputs or in some cases not even included as a potential source of ecological stress.</p> <p>These discussions need to be revised to provide a more accurate and balanced presentation that clearly identifies chemical contamination as a major ecological stressor, and the appropriate focus of a CERCLA BERA, regardless of comparisons to background or reference areas.</p>	<p>The purpose of the baseline risk assessment process is to evaluate whether chemical contamination poses a significant risk to receptors of interest. The purpose of Section 2 is to provide environmental context for the evaluation of risk, given that there are additional stressors in the LPRSA; the purpose of Section 2 is not to evaluate risks associated with contamination, as is done throughout the rest of the BERA, but rather to describe the environmental setting and ecological receptors that utilize the LPRSA. An evaluation of the possibility for chemical risks is provided in the SLERA, where such discussion is more appropriate.</p> <p>Section 2.1 (and other relevant sections) text will be evaluated, revised, and added to in order to reflect that both chemical and non-chemical stressors contribute to risk, as necessary to ensure that readers are clearly aware that chemical contamination is present in the river. However, potential chemical risks are the subject of the rest of the document (outside of Section 2). All language in Section 2 is factual and will be evaluated in context of the remainder of the BERA for balance.</p>	<p>Text revisions to provide a more balanced presentation of stressors are appropriate. The revised document will be reviewed to confirm that EPA's comment has been addressed appropriately.</p>

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10	<p>The uncertainty sections appear to evaluate the impact of other approaches, but such discussions are primarily one-sided. For example, in the evaluation of risks based on fish eggs, alternate HQs are discussed based on the use of a higher, mummichog-specific egg LOAEL, which would result in a lower HQ for dioxins/furans in fish eggs. There is no parallel discussion of alternative HQs if a lower (and likely more appropriate) TRV were to be selected for total PCBs in fish eggs (in which case the HQ would increase about five-fold).</p> <p>Please review the entire document and revise accordingly.</p>	<p>The CPG strongly disagrees with Region 2's contention that the presentation is one-sided. The evaluation of TRVs is based on a strict scientific evaluation to determine if they meet acceptability criteria. If there were studies with lower TRVs that met acceptability criteria, they would have been discussed. The CPG has selected the most applicable TRVs that are technically defensible from appropriate available peer-reviewed studies. If there were lower TRVs from studies that met the criteria, they would have been discussed. See response regarding TRVs in the response to General Comment No. 5.</p> <p>The revised BERA will be evaluated for balance and, if applicable and scientifically defensible, additional text will be added.</p>	<p>The revised document will be reviewed to confirm that EPA's comment has been addressed appropriately. In addition, see response to Comment 5.</p>
11	<p>Setting non-detect values to zero rather than using EPA-approved statistical software (e.g., ProUCL) requires justification beyond just a discussion in the uncertainty sections. It is unclear why a standardized approach is not used throughout the draft BERA. Setting non-detect values to zero may underestimate risks where reporting limits are high. The same approach for addressing non-detect values should be used in both the BERA and the HHRA.</p>	<p>This comment directs the CPG to take an approach inconsistent with previous agreements and documentation related to the handling of non-detect (ND) results for assessing PCB and PCDD/PCDF congener results.</p> <p>The treatment of NDs in the draft BERA is consistent with the methods described in Section 4.1 of the Data Usability Memo (Windward and AECOM 2014), which went through multiple rounds of EPA comments. The Data Usability Memo was submitted to Region 2 on February 26, 2010, a revised draft was submitted on April 13, 2012, and a final revised draft was submitted on May 15, 2014. EPA commented on the document drafts; comments were received on April 1, 2010, and April 10, 2014.</p> <p>A discussion of the impacts on exposure concentrations and risk estimates based on treatment of NDs in sums (as 0, ½, and full DLs) is included in the uncertainty sections of the BERA, including demonstrating that the impact of alternate methods of treatment of NDs would have a negligible impact on risk estimates. The approach taken in the BERA is fully consistent with project-specific plans, guidance, and other sites. The draft BERA uncertainty evaluation regarding the treatment of NDs in sums (as 0, ½, and full DL) is also entirely consistent with the following comment from Region 2 received on April 1, 2010, to the Data Usability Memo: "EPA is still evaluating how best to handle non-detects for congeners with multiple congeners, and Region 2 has contacted Headquarters for further guidance. As such, additional comments on this section will be made at a later date. In the meantime, however, it may be useful to select some examples from the existing dataset to determine the overall impact of using zero, one-half the detection limit, or the full detection limit on the calculated concentrations."</p> <p>As documented in Region 2's June 19, 2015, letter, "During our 5/7/2015 conference call, we came to the conclusion that non-detect values probably were being handled correctly." As discussed with Region 2, a subsection called "Treatment of Non-Detects" be added to Section 4.3 of the revised BERA. Language from Section 5.3 of the May 15, 2014, draft final version of the Data Usability Plan can be used.</p>	<p>Acceptable.</p>
12	<p>The term "unacceptable risk" is never defined in the document. The term should be described in the Executive Summary and in Section 1, as defined in the NCP.</p>	<p>The term is described and defined in terms of how a COPEC becomes a COC and whether, based on ecological significance evaluation of the risk characterization results, there is unacceptable risk at the population level. A definition will be provided in the revised BERA as follows: "unacceptable risk is any HQ greater than one and after review of the ecological significance and the uncertainties of the assessment, it is deemed there is risk to the population."</p>	<p>Any HQ <u>equal to</u> or greater than one indicates unacceptable risk. Unacceptable risk may or may not be linked to ecologically significant adverse effects at the population or community level. It is important to recall that risk equates to potential for adverse effects, and HQs equal to or exceeding one can and should be discussed in the context of ecological significance.</p> <p>EPA requires the use of the following definition from <i>ERAGs (1997 Superfund) text, Page 2-4, Screening-Level Risk Calculation</i>:</p> <p><i>An HQ less than one (unity) indicates that the contaminant alone is unlikely to cause adverse ecological effects.</i></p> <p><i>An HQ or HI less than one does not indicate the absence of ecological risk; rather, it should be interpreted based on the severity of the effect reported and the magnitude of the calculated quotient. As certainty in the exposure concentrations and the NOAEL increase, there is greater confidence in the predictive value of the hazard quotient model, and unity (HQ=1) becomes a more certain pass/fail decision point.</i></p>

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13a	The total TEQs should be evaluated by a calculation of the sum of PCDD/PCDF/PCB TEQs together for each individual sample.	<p>Total TEQs are already presented in the BERA as the sum of all TEF-weighted PCDD/PCDF congeners and dioxin-like PCB congeners on a sample basis, consistent with the methods presented in Table 4-1 and Section 4.1 of the Data Usability Memo (Windward and AECOM 2014), which went through multiple rounds of Region 2 comments. The Data Usability Memo was submitted to Region 2 on February 26, 2010, a revised draft was submitted on April 13, 2012, and a final revised draft was submitted on May 15, 2014. Region 2 commented on the document drafts; comments were received on April 1, 2010, and April 10, 2014. This comment appears to be directing CPG to take an approach inconsistent with previous agreements and documentation with Region 2.</p> <p>It should be noted that the TEQ summation approach applied in both the BERA and BHHRA is consistent with EPA's guidance (EPA 2013).</p> <p>Consistent with Region 2's June 19, 2015, letter, the revised BERA text will include additional language on how TEQs are summed, and will present the totals at the bottoms of relevant tables.</p>	Acceptable.
13b	In addition, evaluation of PAHs in sediment should be conducted using EPA's toxic unit approach, calculated for 34 PAHs.	<p>This comment directs CPG to take an approach inconsistent with previous agreements and documentation. The summing methods for PAHs (as LPAHs, HPAHs, and total PAHs) were presented in the Data Usability Memo (Windward and AECOM 2014), which went through multiple rounds of EPA comments. The Data Usability Memo was submitted to EPA on February 26, 2010, a revised draft was submitted on April 13, 2012, and a final revised draft was submitted on May 15, 2014. EPA commented on the document drafts; comments were received on April 1, 2010, and April 10, 2014.</p> <p>The only comment regarding PAH sums was received by Region 2 on April 1, 2010, on the February 26, 2010, draft of the Data Usability Memo (Windward and AECOM 2014) is the following: "The rationale for inclusion of an alkylated PAH (2-methylnaphthalene) in the PAH totals should be included." CPG consequently removed 2-methylnaphthalene from the PAH sum in the draft sent to EPA on April 13, 2012, and PAH sums were not commented on in EPA's second round of comments on the Data Usability memo received on April 10, 2014.</p> <p>PAH sums in all of the data reports submitted by CPG to Region 2 were summed following the method presented in the Data Usability Memo (Windward and AECOM 2014), and no comments regarding changing the PAH sum were provided by EPA on these data reports, which included: the 2009 fish and blue crab tissue chemistry data for the Lower Passaic River Study Area (last submitted September 19, 2011; Windward 2011), 2010 small forage fish tissue chemistry data for the Lower Passaic River Study Area (last submitted July 18, 2012; Windward 2012a), 2009 and 2010 sediment chemistry data for the Lower Passaic River Study Area (last submitted May 23, 2014; Windward 2014c), and 2011 caged bivalve study data for the Lower Passaic River Study Area (last submitted July 18, 2012; Windward 2012b).</p> <p>As documented in Region 2's June 19, 2015 letter, "During our 5/14/2015 conference call, EPA told the CPG they could use 16 Polycyclic Aromatic Hydrocarbons rather than 34, but that the effects of this should be discussed in the uncertainty section." Therefore, the revised BERA will still report total PAHs as the sum of 16 PAHs, but the effect of summing 16 PAHs rather than 34 PAHs for total PAHs will be discussed as an uncertainty in the BERA.</p>	Acceptable.
14	The SSP2 data must be incorporated into the next draft of the BERA report. Any other RI data not previously included should also be incorporated.	The CPG was explicit during the planning of SSP2 that these data would be included in revisions to 17-mi LPRSA RI/FS Reports. SSP2 data will be included in the revised BERA. All surface water rounds will be included in the revised BERA.	Acceptable.

## Specific Comments

No.	Section	EPA Specific Comment Submitted 5/1/2015	CPG RTC Submitted 9/10/2015 or 9/15/2015	EPA Response to CPG RTC
15	Executive Summary	The Executive Summary will need to be revised once all other comments are addressed.	Appropriate revisions to the Executive Summary consistent with the revised BERA will be made.	Acceptable.
16	Page 1, Section 1	3rd Paragraph: In the last sentence, the reference to NRC 2001 should be removed; 4th Paragraph: The first sentence ("Developing site specific BERA is particularly....") should be deleted.	The CPG does not agree; the statement will be retained for the revised BERA.	EPA accepts that the first sentence of the 4 <sup>th</sup> paragraph will be retained. However, EPA still thinks reference to NRC 2001 is inappropriate and should be removed.
17	Page 2, Section 1	First paragraph: The last sentence of this paragraph should cite to a reference ("Its distinguishing factor....").  Second paragraph: The 7 <sup>th</sup> sentence of this paragraph ("USEPA also identified....") makes it sound like all of contaminants listed come from Lister Avenue. Please modify so that the language is included as part of a discussion of other industrial sources of contaminants along the lower Passaic River.  Second paragraph: The last 4 sentences of this paragraph should be deleted and a sentence added to summarize this information, so that the last 2 sentences of this paragraph become: "The property itself was identified as operable unit (OU)-1 of the Diamond Alkali Superfund site. Subsequent investigations in the Passaic River and Newark Bay have been undertaken as additional operable units."	The discussion of COPCs presented in the BERA is consistent with Region 2's presentation of the site history and list of contaminants presented in the April 2014 FFS/RI and appendices.	Upon further consideration the EPA is willing to withdraw this comment and accept the CPGs response of no action.
18	Page 11, Section 2.1	In the last sentence of the 2 <sup>nd</sup> paragraph of this section, please replace the words "extensively restricted" with "limited" for consistency with the RARC.	Comment can be incorporated into revised document.	Acceptable.
19	Page 12, Section 2.1	Please provide a citation for the statement in the last sentence of the 2 <sup>nd</sup> paragraph of this page ("The frequent and intense disturbance....").	Comment can be incorporated into revised document. Citation is Iannuzzi et al (2002).	Acceptable.
20	Page 15, Section 2.1.1	Missing from the discussion of the influence of non-chemical stressors is acknowledgement that for a tidally influenced environment, some of the factors mentioned (wide fluctuations in salinity, freshwater flow, turbidity, OC content, some nutrient inputs) are natural conditions of an estuarine environment for which the native biota are well adapted. However, native receptors may become excessively stressed by man-made influences from both chemical and physical modifications to the system.	Comment can be incorporated into revised document.	Acceptable.
21	Page 21, Section 2.1.1.3, second paragraph	The text indicates that carp are responsible for a wide variety of impacts on the Passaic River. The text does not supply any site-specific information, such as chlorophyll a measurements with and without carp, and there is no discussion regarding other sources that could impact the river in similar ways, such as Canada geese, mallard ducks, etc. This discussion should be removed from the document.	The CPG disagrees with this comment and will retain this language, as it is critical information in understanding the site-specific CSM. The CPG will note this information (including any relevant information regarding other species, such as Canada geese and mallard ducks, as relevant) is supported by the literature, rather than removing discussion entirely from the document. This is important information for the ecology of the site and is appropriate in Section 2. This response also applies with regard to Appendix N (Comment No. 23).	EPA does not accept the CPG's comment. The text in this section suggests that because literature has been cited that shows in some situations carp can increase turbidity, that they are the source of turbidity and impacts in the Passaic River. There is no site-specific information showing that turbidity is increased in the Passaic River and no data on potential sources of turbidity, such as tidal influences and CSOs.  Furthermore, numerous other species can impact local environments. These impacts can be negative, positive, or neutral. Limiting this discussion to carp or to a few other non-native species is incomplete and inappropriate. Many ictalurids and other benthic fish can contribute to mobilization of surface sediment while foraging. This discussion should be complete and well-rounded, or eliminated from the document.
22	Page 25, Section 2.1.1.7	Additional information should be added to this section to provide a historical and seasonal perspective on DO concentrations, as well as a discussion on current conditions, if known.	Comment can be incorporated into revised document, to the extent the data are available to do so.	Acceptable.



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23	Page 27, Section 2.1.1.8, second paragraph	There are no site-specific data to support the conclusions made in Appendix N and there is a lack of information on other sources that could have similar impacts. The entire appendix should be deleted, and this paragraph should be removed from the document.	See response to Comment No. 21. CPG does not agree that Appendix N should be deleted and will provide additional literature citations to support the statements and conclusions, as well as Appendix N.	See response to Comment No. 21. Citing literature will only provide support for half of the problem. The main issue is that conclusions about site-specific effects in the Passaic River are being made and there is no site-specific data to support these claims. Due to this, EPA stands by its comment that Appendix N must be deleted from the document.
24	Page 27, Section 2.1.2.1	The phrase “small patches or isolated areas” inadequately describes mudflat areas in this river and diminishes their importance as preferred avian forage areas. Mudflats are a significant feature of interest in this river for both ecological habitat and contaminant accumulation. For this reason, improved description of the areal extent of mudflats in the LPRSA is needed. Either in this section, or elsewhere in the report, each mudflat area needs to be identified and described based on dimensions (overall acreage and/or length along the riverbank).	Mudflats are described and the definition of mudflats has been discussed and agreed to with Region 2. To assist the reader, a table will be prepared in the Revised BERA that characterizes each mudflat in terms of area and grain size.	Acceptable.
25	Page 28, Section 2.1.2.2	The statement that “very little” riparian habitat exists is imprecise and subjective. Please clarify.	A complete habitat survey was conducted and this statement is one of the concluding notes from that survey. This will be noted in the text.	Acceptable.
26	Page 36, Section 2.2.1	The benthic salinity zones identified on this page are different from the salinity zones identified on Page 16. The differences between designating these zones based on salinity of sediment and salinity of surface water need to be discussed and additional text should be added to discuss the impacts of these differing designations on estimated risks.	The definitions are noted in the text, per receptor group. This will be highlighted and discussed in more detail for the reader.	Acceptable. As noted in the BERA, salinity exerts a strong influence on the distribution of aquatic organisms. Therefore, it is critical that salinity zones based on water column and benthic salinity are clearly defined. Currently, the river is treated as a single, composite unit, but the three salinity zones are delineated two different ways. Therefore, estimated risk based on salinity zone could differ based on individual receptors.

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27	Page 39, Section 2.2.1.1, and page 42, Table 2-2	<p>This section and table indicate that the most abundant BMI are worms, primarily polychaetes and oligochaetes, depending on the salinity of the water at the sampling stations. Given this dominance, it is important to recognize that these organisms live and forage in sediments over a fairly wide range of depths (e.g., many polychaetes burrow within the upper 10 cm of sediment, but some burrow much deeper), and that restricting the biologically active layer of sediments to the upper few cm (as noted throughout the document) is inappropriate for estimating sediment-associated risks.</p> <p>Please make the appropriate changes throughout the document.</p>	<p>As stated multiple times to Region 2, the BERA WOE-based assessment of invertebrate risks is based entirely upon sediment chemistry, community, and toxicity data for sediments collected to a depth of 15 cm. In this section, CPG is providing information on the species surveys and the literature on burrowing depths. CPG requests that Region 2 provide the references that support the “(e.g., many polychaetes burrow within the upper 10 cm of sediment, but some burrow much deeper)” and the LPRSA site-specific information that supports this statement.</p> <p>Review of any citations from Region 2 can be incorporated into the revised BERA, as relevant.</p>	<p>The following information supports the position that, in the absence of chemical avoidance, polychaetes commonly burrow to depths beyond 2 cm. There is no site-specific evidence that polychaetes, oligochaetes and possibly other benthic invertebrates would not burrow deeper in the LPRSA if the sediments were not contaminated (i.e., if avoidance was not taking place), and an observed lack of abundance at greater depths may simply reflect avoidance behavior. Further, the 2005 Aqua Survey, Inc. <i>Sediment Profile Imaging Survey of Sediment and Benthic Habitat Characteristics of The Lower Passaic River</i> found feeding voids greater than 2cm at 29 out of the 30 locations where feeding voids were identified.</p> <p><b>ABSTRACT:</b> Ragworms <i>Nereis diversicolor</i> live in burrows which, if deeper than 5 to 10 cm, offer a safe refuge from most of their predators. Burrow depth must be ca 15 cm before they live out of reach of all predators. Burrow depth increases with body size, levelling off at ca 15 cm, when the depth refuge is reached. Worms live at greater depths in sand than in mud, but this effect disappears if worms with identical body condition (expressed as deviation from mean body weight for a given body length) are compared. Seasonal variation in burrow depth is correlated with sea temperature and to a lesser extent with day length and body condition. Feeding worms are present near or at the surface. Filter feeding occurs in the first 2 h after exposure (at least if a water film still remains at the surface) and surface feeding begins after that. The total time spent at the surface does not exceed an average of 50 s per tidal cycle. Feeding must be an extremely risky activity, because predators readily catch most <i>N. diversicolor</i> while present near or at the surface.</p> <p><b>Esselink and Zwarts. 1989. Seasonal trend in burrow depth and tidal variation in feeding activity of <i>Nereis diversicolor</i>. Mar. Ecol. Prog. Ser. Vol. 56: 243-254, 1989</b></p> <p>*****</p> <p>The physical dimensions of macrofaunal burrows vary considerably, depending on the species and the environment (<b>Table 1</b>). The depth distribution of burrows in sediments varies from a few centimeters for small species and juveniles to several decimeters for many adult polychaetes and more than 3 m for large crustaceans (e.g. mud lobsters) [Pemberton et al., 1976; Rhoads and Boyer, 1982].</p> <p><b>Kristensen and Kostka. 2000. The Ecogeomorphology of Tidal Marshes. Coastal and Estuarine Studies 59. Copyright 2004 by the American Geophysical Union</b></p> <p><b>Modified from Table 1 – Kristensen and Kostka, 2000.</b></p> <table><tr><th>POLYCHAETA</th><th>Burrowing Depth (cm)</th></tr><tr><td><i>Nereis virens</i></td><td>30–50</td></tr><tr><td><i>Nereis diversicolor</i></td><td>15–20</td></tr><tr><td><i>Ranzanides saggittaria</i></td><td>8–10</td></tr><tr><td><i>Arenicola marina</i></td><td>20–40</td></tr><tr><td><i>Amphitrite ornate</i></td><td>25–35</td></tr><tr><td><i>Lanice conchilega</i></td><td>5–10</td></tr></table>	POLYCHAETA	Burrowing Depth (cm)	<i>Nereis virens</i>	30–50	<i>Nereis diversicolor</i>	15–20	<i>Ranzanides saggittaria</i>	8–10	<i>Arenicola marina</i>	20–40	<i>Amphitrite ornate</i>	25–35	<i>Lanice conchilega</i>	5–10
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28	Page 51, Figure 2-19	Please show this figure for each category of benthos (e.g., detrivore, etc.).	This will be completed in the Revised BERA.	Acceptable.														
29	Page 56, Section 2.2.1.4	It appears that the method used to determine successional stage results in disagreement with the SPI data. Please provide some comparison of these results to the SPI results and explain the rationale for selecting one method over another.	<p>It is not possible to select a one method over the other because SPI imagery was not collected at the sampling locations in question. Germano and Associates collected SPI data in 2005, and community data was collected primarily in 2009 (with some resampling in 2010). The 2005 sampling locations were not reoccupied in 2009–2010.</p> <p>In general, similar trends were observed in community stages throughout the LPRSA using the various analysis methods and datasets. This successional stage information will be reviewed and edited as necessary in the revised BERA.</p>	The revised document will be reviewed to confirm that EPA’s comment has been addressed appropriately.														

No.	Section	EPA Specific Comment Submitted 5/1/2015	CPG RTC Submitted 9/10/2015 or 9/15/2015	EPA Response to CPG RTC
30	Page 62, Section 2.2.2 and Table 2-3	<p>The text indicates that only a “very small number of other invertebrates encountered were either bivalves (n = 2 organisms) or gastropods (n = 1)”. In addition, Table 2-3 identifies clams as “unspecified”. This is inconsistent with the text in Section 2.2.1.3, which indicates that the clam <i>Corbicula</i> are relatively common, and even “highly abundant” above RM 7.3. In addition, other species of bivalves are present in the LPRSA based on the benthic surveys conducted in 2009 and 2010.</p> <p>Please revise, as appropriate.</p>	<p>The text on page 62 and in Table 2-3 describes the results of the fish and (epifaunal) decapod survey that was conducted in 2009 and 2010, which is not the same survey as the benthic community survey of sediments (and infauna). The “very small number of other invertebrates” were found in traps intended to capture large, epifaunal decapod species.</p>	<p>The response is not adequate. Additional text must be added that explains the fish and epifaunal decapod survey were not designed to identify small epifaunal decapod species, thus the lack of these species encountered during the survey is not meaningful.</p>
31	Pages 63-66, Section 2.3	<p>This section inadequately summarizes some of the results of the 2009-2010 fish surveys. The counts of the most commonly collected benthic omnivorous fish shown on Table 2-4, from most to least, are mummichog (1,696), American eel (743), striped killifish (412), banded killifish (359), common carp (215), and bluegill (146). In Section 2.3.1, it is correctly stated that killifish (all taxa) and small American eel dominate the benthic omnivore fish community. Of the more commonly collected benthic omnivorous fish, only common carp and eel are likely to routinely attain a size large enough to serve as prey for larger piscivorous predators (and possibly humans). Inclusion of larger benthic omnivorous fish such as carp in discussions of exposed ecological receptors (and in risk estimation) is critical, especially since carp are potentially among the most highly exposed types of fish (fatty, long-lived, and intimately associated with sediments).</p> <p>Please make the appropriate changes here and throughout the document.</p>	<p>CPG disagrees with this comment. See response to General Comment No. 3. Region 2 directed the CPG to analyze only very large carp that are too big to be consumed by many ecological receptors (also see Table 2 and Figure 1, attached separately). The BERA presents the fish counts by reach, which is the purpose of this section (i.e., to summarize the information collected).</p> <p>The statement that “Of the more commonly collected benthic omnivorous fish, only common carp and eel are likely to routinely attain a size large enough to serve as prey for larger piscivorous predators (and possibly humans). Inclusion of larger benthic omnivorous fish such as carp in discussions of exposed ecological receptors (and in risk estimation) is critical,” is not supported by the literature. As cited in the BERA, wildlife feed primarily (if not exclusively) on smaller fish.</p> <p>The CPG also questions the need and appropriateness to mention that only carp and eel reach sufficient size to serve as prey for humans—this document is an ecological risk assessment. The potential human health risk associated with carp and eel is detailed in the June 2014 17-mi BHHRA.</p> <p>As presented in the approved PFD, carp are not an ecological receptor. They are an added stressor to the LPRSA due to their destructive habitats and out competing native fish (See Appendix N of the BERA).</p>	<p>See other relevant responses regarding inclusion of carp data in evaluations of fish. Considering carp as a stressor and not a receptor is highly inappropriate. The memorandum “Revised Sample Analysis Plan for Catfish/Bullhead, Carp, Bass, White Sucker, and Northern Pike Tissue for the Lower Passaic River Restoration Project (Revised Fish Sample Analysis Plan, Part 1)” dated May 21, 2010 specifically indicates that carp will be evaluated in the BERA and identifies that carp were included as an alternate species. The CPG must make the changes as directed by EPA regarding evaluating carp in the BERA.</p>
32	Page 64, Table 2-4	<p>Alewife is a planktivore, not a benthic omnivore. Please revise the table to reflect this.</p>	<p>Comment can be incorporated into revised document.</p>	<p>Acceptable.</p>
33	Page 67, Section 2.3.1	<p>Unless described elsewhere, the stage of life and timeframes (length of time, frequency and sediment depth) that American eel are likely to interact with Passaic River bed sediment should be described for improved perspective on potential exposure to contaminated media in the study area.</p>	<p>Comment can be incorporated into revised document.</p>	<p>Acceptable.</p>
34	Pages 71 to 72, Section 2.3.6	<p>This section should include additional information on the life cycle of the target fish species (per feeding guild, and especially for those found most abundantly such as the White Perch, American eel and others) relative to their expected time spent in the Lower Passaic River. If this information is provided elsewhere, a citation here is appropriate.</p>	<p>Comment can be incorporated into revised document.</p>	<p>Acceptable.</p>

No.	Section	EPA Specific Comment Submitted 5/1/2015	CPG RTC Submitted 9/10/2015 or 9/15/2015	EPA Response to CPG RTC
35	Page 72, Figure 2-25	This is a typical food pyramid with predators on top and producers on the bottom. It is not consistent with just an urban river, but with all aquatic systems (terrestrial too). Please revise the last paragraph on this page to clarify.	The food pyramid does not present any “producers,” only species that feed lower on the food chain than predators (i.e., on detritus or invertebrates). Shifts in trophic status as a result of urbanization and reduced water quality have been observed in the literature (Eitzmann and Paukert 2010; McIntyre et al. 2006; Adams and Paperno 2012). Although it is often true that smaller species lower on the food chain are generally more abundant than larger species, in the case of the LPRSA, many of those species low on the food chain are quite large (e.g., common carp); the benthic omnivore group is also quite diverse (i.e., abundance based on sum of many species rather than larger populations of few r-selected species).  More text will be added, but note this is a pyramid typical of an urban system—more information will be provided to support this statement.	Acceptable, with reservations that this pyramid not be identified as highly unique.
36	Page 72, Section 2.3.6, last paragraph, last sentence	The text states that benthic fish “exploit” settling solids coming from impervious surfaces and CSOs. Assuming this implies feeding, additional text should be added to include solids that are constantly suspended by tides and other forces and are contaminated with site-related chemicals.  In addition, this entire sentence is drawing conclusions about urban rivers in general. Please add a citation to support this, or remove the statement.	Will replace “exploit” with “utilize” in conjunction with inputs from local resuspension of solids and tidal action.	Acceptable, and a citation still needs to be included.
37	Page 73, Section 2.4	This section states: “The LPRSA provides limited and fragmented habitat for avian species. There are limited mudflats for sediment-probing birds and some riparian habitat for species inhabiting the shoreline, and significant marsh habitat is largely absent from the LPRSA shoreline....”  While there are limited mudflats, this condition needs to be placed in context of the wider area, in that the available mudflats, which constitute at least 30% of the shoreline habitat, are quite important to the receptors that utilize them. Relative to the densely developed surrounding land use, the available mudflats are of prime importance to avian species in the area.	The CPG agrees that the mudflats are of prime importance to receptor species that forage on them; nonetheless, LPRSA mudflats are fragmented and limited due to the urbanization and development of the LPRSA  Additional relevant information and context will be included in the revised BERA, as well as a summary of the site-specific surveys that the CPG conducted.	Acceptable. The revised document will be reviewed to confirm that EPA’s comment has been addressed appropriately.
38	Pages 74-75, Table 2-5	Double-crested cormorant, belted kingfisher and boat-tailed grackle are listed on the table; however, it is not indicated in which seasons these birds were observed. Please revise the table as appropriate.	Comment can be incorporated into revised document.	Acceptable.
39	Page 77, Section 2.4.2, first paragraph, last sentence	Canada geese do breed on the Passaic River; their young and nests have been observed. Please revise the text to reflect this.	Comment can be incorporated into revised document based on the immature Canada geese observed in the LPRSA during the avian surveys; however, documentation/citations regarding their nesting in the LPRSA is requested by CPG from Region 2.	Acceptable. Please cite personal communication from Chuck Nace for this observation. Additional information (photographs), if needed, will be provided in May 2016 during the nesting season.
40	Page 80, Section 2.4.5, first full paragraph, last sentence	Cormorants do nest in Newark Bay. Please revise the text to reflect this.	Comment can be incorporated into revised document. Please note, however, that CPG is unaware of any studies documenting cormorants nesting in the LPRSA.	Acceptable. Cormorant nests were observed during an avian reconnaissance survey in Newark Bay conducted as part of the Newark Bay investigation in 2014. See attachment titled <i>Newark Bay Study Area Reconnaissance Survey Report</i> , dated April 2015 (see attached, 2015-04 NBSA Recon Report Bird Nest Excerpt Tierra.pdf)
41	Page 81, Section 2.5, fifth sentence	The only species of chipmunk that exists on the east coast is <i>Tamias striatus</i> ; please substitute this species for “unidentified species of chipmunk.” There are also seals in the area; please revise the text to reflect this.	Documents and citations supporting the presence of seals in the LPRSA is requested from Region 2 to support this comment.  Chipmunk species will be added. No change will be made regarding seals unless sufficient authoritative documentation is provided.	EPA’s comment notes that seals are in the area, not specifically that they are in the Passaic River. Text should be added that states “Several species of seals (e.g., harbor, gray, harp and hooded) winter in the NY/NJ Harbor, which is near the LPRSA. While it is unlikely that seals would spend significant time in the LPRSA, they may be infrequent visitors.” <a href="http://www.hackensackriverkeeper.org/harbor_seal.html">http://www.hackensackriverkeeper.org/harbor_seal.html</a>

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42	Page 81, Section 2.5, last sentence	Please add the phrase “there may be” to the conclusion regarding “insufficient riparian tree and shrub cover in the LPRSA....”	Comment can be incorporated into revised document.	Acceptable.
43	Page 82, Section 2.6 and Table 2-6	There is potential for sea turtles to use the saline portion of the Passaic River. Please add sea turtles to the text and table.	<p>The CPG disagrees that reptiles will be found in the lower 4 mi of the LPRSA. There is a low likelihood of encountering reptiles in the estuarine portion of the LPRSA, given the poor quality of turtle habitat there and in the surrounding region, and we have seen no evidence to suggest otherwise (there is little documented recent evidence of marine turtle presence in the New York and New Jersey Harbor, as cited by NOAA: <a href="http://www.greateratlantic.fisheries.noaa.gov/hcd/EFH%20NB-KLN.pdf">http://www.greateratlantic.fisheries.noaa.gov/hcd/EFH%20NB-KLN.pdf</a>). Reptiles were only spotted during surveys of freshwater portions of the LPRSA and above Dundee Dam. Anecdotal evidence present online also suggests that reptiles are present upstream of the LPRSA.</p> <p>In addition, this comment directs CPG to take an approach inconsistent with Region 2’s own FFS ERA Appendix D Section 4.1.3, pages 4-15 (Louis Berger et al. 2014), wherein Region 2 stated: “the presence of amphibians and reptiles is not well documented in the FFS Study Area and there appears to be little viable habitat to support this ecological group.”</p> <p>No change will be made to the revised BERA.</p>	This section identifies potential species that could be found in the LPRSA. Sea turtles could access the LPRSA although it is unlikely that the LPRSA provides adequate habitat or conditions to support this ecological receptor group. The following text should be added: “Several species of sea turtles could be found in the NY/NJ Harbor estuary, which is near the LPRSA. While it is unlikely that sea turtles would spend significant time in the LPRSA, they may be infrequent visitors, although the LPRSA would not provide adequate habitat or conditions to support this ecological group.”
44	Pages 91-96, Table 3-2	Risk questions (hypotheses) associated with Assessment Endpoints presented on Table 3-2 are in some cases inconsistently worded. Please revise so that all are worded the same.	<p>This comment directs CPG to take an approach inconsistent with previous agreements and documentation. Language of risk questions is consistent with the Region 2-approved PFD (Windward and AECOM 2009). See Table 5-2 of the PFD (Windward and AECOM 2009). The PFD went through multiple rounds of review by Region 2 and was approved on July 31, 2009.</p> <p>As documented in Region 2’s June 19, 2015, letter, any changes to the risk questions associated with Assessment Endpoints presented in Table 3-2 are no longer required by Region 2.</p> <p>No changes will be made to the revised BERA.</p>	As is noted in EPA’s 6/19/2015 letter, to maintain consistency with the wording used in the PFD, no changes to the table are required.
45	Pages 93-94, Table 3-2	Notable for its absence under Assessment Endpoint No.5 is the risk question that considers risks to fish from exposure to sediment-associated contaminants. Benthic fish are likely to be significantly exposed to sediment-associated contaminants via exposure routes involving prey, surface water, porewater, and sediment, yet sediment is not evaluated for the assessment endpoints related to protection of fish. It is recognized that concentrations of contaminants in sediment are difficult to apply to a quantitative evaluation of risks to fish. However, retaining and fully evaluating contaminant concentrations in the whole body of all fish species collected, including carp, is prudent given the strong likelihood of exposure to potentially contaminated sediment for these receptors (the CSM shows ingestion of sediments as a complete and major exposure pathway for benthic fish). The BERA should evaluate contaminant concentrations in all biological tissues collected and analyzed.	<p>This comment directs CPG to take an approach inconsistent with previous agreements and documentation. Language of assessment and measurement endpoints used in the BERA is consistent with the Region 2-approved PFD (Windward and AECOM 2009). See PFD Table 5-2 (Windward and AECOM 2009). The PFD went through multiple rounds of review by Region 2 and was approved on July 31, 2009. Also see BERA Tables 3-2 and 5-1 and Sections 4.3.4 and 7.1.6.</p> <p>In addition, the statement that sediment-associated contaminant exposure “is notable for its absence” is incorrect given that whole-body fish tissue (which evaluates all routes of exposure) was evaluated in the BERA for all fish species, except carp.</p>	A major concern reflected by the initial comment is the “except carp” item in the CPG response. Carp should not be excepted. Furthermore, the CPG fails to acknowledge that additional decisions were made after the approval of the PFD in 2009. The memorandum “Revised Sample Analysis Plan for Catfish/Bullhead, Carp, Bass, White Sucker, and Northern Pike Tissue for the Lower Passaic River Restoration Project (Revised Fish Sample Analysis Plan, Part 1)” dated May 21, 2010 specifically indicates that carp will be evaluated in the BERA and identifies that carp were included as an alternate species. The CPG must make the changes as directed by EPA regarding evaluating carp in the BERA.
46	Page 95, Table 3-2, Notes	<p>The first footnote indicates that “additional data will be collected on conventional parameters...” Please clarify.</p> <p>In addition, please provide more information to help clarify what is meant by footnote d.</p>	<p>A clarification will be made in the revised BERA to note data were collected on additional parameters.</p> <p>Language of footnote “d” in Table 3-2 is consistent with the Region 2-approved PFD (Windward and AECOM 2009). See “Note” and footnote “e” in PFD Table 5-2 (Windward and AECOM 2009). The PFD went through multiple rounds of review by Region 2 and was approved on July 31, 2009.</p>	Acceptable.

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47	Page 104, Section 3.3.2	The 4 <sup>th</sup> sentence of the last paragraph on this page should be deleted (“Impacts related to urban stress...”). It is making premature and potentially false conclusions.	The CPG disagrees that these statement are premature and potentially false. These are factual statements. Given the context of the LPRSA within an urban setting, these statements in the description of the CSM help the reader in understanding the system. It would be irresponsible and misleading to leave these types of statements out of the document.  No changes will be made to the revised BERA.	Although the general statements are factual based upon the aquatic systems studied in the references, the text concludes that similar effects are occurring in the Passaic River without providing site-specific evidence. By emphasizing that non-chemical stressors are so deleterious to fish population and food web dynamics, it becomes misleading by suggesting that these effects outweigh chemical stressors. If anything, these are synergistic effects that are not mutually exclusive from one another. While the context of an urban river is important, it should not overshadow the fact that chemicals are present in the system and are also potentially contributing to risk in the LPRSA.  EPA maintains that this sentence should either be deleted, or at a minimum clarified to reflect the above.
48	Pages 106 to 201, Section 4.2	The Data Quality Objectives for the BERA dataset specify that the “data must represent current conditions” but the data from the proposed reference and background locations do not all meet this objective. In particular, the proposed estuarine background/reference samples were collected well before 2007, including: sediment chemistry data were collected as early as 1993, sediment toxicity data go back to 1999, tissue chemistry data dates back as far as 1978 and biological survey data go back to 1993.  More text is needed at the beginning of this section explaining the rationale for including these older data, but that the use of them introduces uncertainty. Then, the uncertainty associated with the use of these data should be explained in Section 7.1, where appropriate.	This comment directs CPG to take an approach inconsistent with previous agreements and documentation.  The background and reference area data were extensively discussed with Region 2. The freshwater background data (from the UPR) are based on current data collected in 2012 using an approved Region 2 QAPP; available regional estuarine data for sediment and tissue are limited and based on older datasets. These data would also eliminate some of the Mullica River that Region 2 and its Partner Agencies have insisted that CPG use. It should be noted that Region 2 relied on older datasets in its 2014 FFS/RI. Per Section 3 of the Data Usability Memo (Windward and AECOM 2014), the DQOs established for the BERA are based on data collected from the Study Area for the derivation of risk estimates; data that do not meet these DQOs may still be used for other purposes (e.g., comparison to background).  Ideally, current data are used for background and reference areas; however, given the availability of regional data for potential use as background and reference area data, the evaluation relied on data collected from the 1990s to the present. Background and reference data from the 1990s to the present are assumed to be reasonable, given that analytical methods used during this time frame are considered comparable to the analytical methods currently used. It should also be noted that the cited 1978 study (for mummichog tissue) listed in Table 4-3 of the BERA was actually not used in any tissue comparison to background. These data will be taken out of this table summary.  Text will be added to point the reader to the summary of agreements with Region 2 regarding review and use of regional available data.	The CPG did not understand EPA's comment. EPA is not directing the CPG to take an approach that is inconsistent with previous agreements. EPA is simply asking for additional information to be included in two sections of the document. The first is to describe the rationale for including older data, which was provided in the third paragraph of the response, in Section 4.2. The second is to discuss in the uncertainty section how using older data may have impacted the evaluation.  A summary of agreements with EPA should be added to the text.
49	Pages 172 to 173, Table 4-4	The table should clarify whether fraction dissolved data for both organic and inorganic contaminants were used in the risk assessment, and some discussion should be added here and possibly in the uncertainty section.	Surface water data were evaluated based on dissolved concentrations, unless criteria are based on total concentrations. Therefore, both dissolved and total concentrations are presented in this general data table.  Additional discussion will be added to the revised BERA.	Acceptable.
50	Page 185, Figure 4-30	Seines were used to capture fish also. Please add the seine locations to the figure.	Comment can be incorporated into revised document.	Acceptable.

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51	Page 206, Section 4.3.3.1	A set of rules should not be used to determine what value to use when multiple values are available. Instead of a set of rules, each value that has multiple results should be evaluated and the most appropriate value should be used. High- resolution methods are not superior to the low resolution method. A table listing the samples with their multiple results, along with a column for rationale of which value is chosen should be included.	<p>This comment directs CPG to take an approach inconsistent with previous agreements and documentation. The data rules for selecting a single value when multiple values are reported were presented in Section 4.2.1 of the Data Usability Memo (Windward and AECOM 2014) and a number of data reports, all of which went through multiple rounds of Region 2 comments. The Data Usability Memo was submitted to Region 2 on February 26, 2010, a revised draft was submitted on April 13, 2012, and a final revised draft was submitted on May 15, 2014. Region 2 commented on the document drafts; comments were received on April 1, 2010, and April 10, 2014. No comments were provided by Region 2 regarding data rules for selecting single values when multiple results were reported.</p> <p>Data reports submitted by CPG to Region 2 applied this data rule in the selection of single results. These data reports include the 2009 fish and blue crab tissue chemistry data for the Lower Passaic River Study Area (last submitted 9/19/11; Windward 2011), 2010 small forage fish tissue chemistry data for the Lower Passaic River Study Area (last submitted July 18, 2012; Windward 2012a), 2009 and 2010 sediment chemistry data for the Lower Passaic River Study Area (last submitted May 23, 2014; Windward 2014c), and the 2011 Caged bivalve study data for the Lower Passaic River Study Area (last submitted July 18, 2012; Windward 2012b). Region 2 did not provide comments regarding this data rule in these data reports.</p> <p>The data rules followed for selecting values to use when multiple values are available will be explicitly included in the revised BERA so that the BERA can serve as a standalone document.</p>	The CPG did not understand EPA's comment. EPA is asking for additional discussion to explain how following the rules could impact the results of the risk assessment. The data can be evaluated to determine if the single values that were chosen were consistently lower, higher or roughly the same as the values that were not chosen. If the values were on average lower, then risk would be potentially underestimated; if on average they were higher, then risk would be potentially overestimated; and if on average they were the same, the risk would be an accurate representation.
52	Page 207, Section 4.3.3.2	The rules provided for evaluating the field duplicates and laboratory replicates are generally acceptable; however, for values that fall under the first bulleted rule, a table should be created that shows both values to confirm that the results are not vastly different. If the values are vastly different, then additional text should be provided to explain why averaging the results is valid.	<p>Despite the impracticality of this comment (i.e., the level of detail for data documentation required in the BERA, rather than in the previously submitted data reports), this comment directs CPG to take an approach inconsistent with previous agreements and documentation. The data rules for evaluating field duplicates and lab replicates were presented in Section 4.2.2 of the Data Usability Memo (Windward and AECOM 2014) and a number of data reports, all of which went through multiple rounds of Region 2 comments. The Data Usability Memo was submitted to Region 2 on February 26, 2010, a revised draft was submitted on April 13, 2012, and a final revised draft was submitted on May 15, 2014. Region 2 commented on the document drafts; comments were received on April 1, 2010, and April 10, 2014. No comments were provided by Region 2 regarding data rules for treatment of field and lab replicates.</p> <p>The treatment of laboratory replicates was applied in the data reports submitted to Region 2. Also, it should be noted that the data reports submitted by CPG to Region 2 present all reported field duplicate results (i.e., sediment field duplicates). These data reports include the 2009 fish and blue crab tissue chemistry data for the Lower Passaic River Study Area (last submitted September 19, 2011; Windward 2011), 2010 small forage fish tissue chemistry data for the Lower Passaic River Study Area (last submitted July 18, 2012; Windward 2012a), 2009 and 2010 sediment chemistry data for the Lower Passaic River Study Area (last submitted May 23, 2014; Windward 2014c), and the 2011 caged bivalve study data for the Lower Passaic River Study Area (last submitted July 18, 2012; Windward 2012b).</p> <p>The data rules followed for evaluating field duplicates and laboratory replicates will be explicitly included in the revised BERA so that the BERA can serve as a standalone document.</p>	The CPG did not understand EPA's comment. EPA is asking for additional discussion to explain how following the rules could impact the results of the risk assessment. The data can be evaluated to determine if the single values that were chosen were consistently lower, higher or roughly the same as the values that were not chosen. If the values were on average lower, then risk would be potentially underestimated; if on average they were higher, then risk would be potentially overestimated; and if on average they were the same, the risk would be an accurate representation.

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53	Page 208, Section 4.3.5, third paragraph	The text states that mussel tissue data were normalized by subtracting the final field-exposed mussel concentrations from the control concentrations (Day 0). This approach is unacceptable. The approach should be to report contaminant concentrations at Day 0 and at the end of the exposure period. Please make the necessary corrections.	<p>The CPG disagrees that Day 0 concentrations should not be accounted for in defining EPCs for the caged mussels. The revised BERA will clarify that the control (Day 0) concentrations were subtracted from the final field-exposed mussel concentration (not that the final concentrations were subtracted from the control). The point of taking Day 0 tissue concentrations is to normalize the data. The bivalves were raised outside the LPRSA and, prior to deployment, received body burdens from their holding area, which was not in the LPRSA. It is not CPG and Regions 2's responsibility to assess risk to organisms that received a chemical load from outside the study area.</p> <p>No accounting for control concentrations is inconsistent with the purpose of the mussel collection effort, as documented in the March 2011 Caged Bivalve Study QAPP Addendum (Windward 2011a) and the July 2012 CBS Report (Windward 2012b). In addition, as documented in the approved QAPP (Worksheet No. 9; Windward 2011a), Region 2 indicated that no quantitative evaluation of the data is required and it can be discussed in the uncertainty section of the BERA.</p>	A table that shows the Day 0 concentrations, final concentrations and the difference between Day 0 and the final concentration must be added to the report. Presenting Day 0 and final concentrations will allow for comparisons of LPRSA and non-LPRSA contributions to bivalve tissue concentrations.
54	Pages 211 to 213, Section 5	<p>The primary objective of a SLERA is to determine if there is a likelihood for ecological impacts based on conservative assumptions and screening values and to determine if a BERA is warranted. The main finding of the SLERA is that a BERA should be completed. The second paragraph on page 211 should be deleted and replaced with the following text:</p> <p>"The primary objective of the SLERA was to provide information to the risk manager to determine one of three options:</p> <p>(1) There is adequate information to conclude that ecological risks are negligible and therefore there is no need for remediation on the basis of ecological risk; (2) The information is not adequate to make a decision at this point, and the ecological risk assessment process will continue to Step 3; or (3) The information indicates the potential for adverse ecological effects, and a more thorough assessment is warranted." This entire section will need to be revised based on comments on Appendix A.</p>	The CPG fails to understand the point of this comment; Region 2's notes and the CPG paragraph essentially say the same thing. No change will be made to the revised BERA.	EPA's comment reflects the language presented in EPA's guidance document titled "Ecological Risk Assessment for Superfund: Process for Designing and Conducting Ecological Risk Assessments." The text supplied by EPA must be used.
55	Page 212, Table 5-1 and Section 5.2	Carp should be included in this table, specifically as a representative benthic omnivorous fish, and included in the evaluation described in this section.	<p>CPG disagrees with this comment. See response to General Comment No. 3.</p> <p>This comment directs CPG to take an approach inconsistent with previous agreements and documentation. Carp were not included as representative fish in the Region 2-approved PFD (Windward and AECOM 2009). See PFD Table 5-1 (Windward and AECOM 2009). The PFD went through multiple rounds of review by Region 2 and was approved on July 31, 2009. Common carp were also not identified as a target or alternate species in the Fish and Decapod QAPP (Windward 2009a); carp that were caught during the 2009 fish sampling program were kept at the direction of Region 2, per the June 30, 2009, call. As documented in Worksheet No. 9 on page 35 of the Fish/Decapod Tissue QAPP (Windward 2009a), it was agreed during this call that carp did not need to be added as a target species.</p>	Refer to numerous other comments on inclusion of carp as a valid ecological receptor.
56	Page 215, Section 5.4, second paragraph	COIs with screening level HQs greater than or equal to 1, not just greater than 1, should be retained for further investigation in the BERA. This comment also applies to numerous other locations in the draft BERA where HQ > 1 is stated to be the "unacceptable" threshold; the threshold should be HQ ≥ 1.	For the revised BERA, COIs with HQs ≥ 1 will be retained in the SLERA. In the BERA evaluation, if a chemical dose is equal to the TRV, the implications of this will be discussed relative to the TRV and the exposure does.	The revised document will be reviewed to confirm that EPA's comment has been addressed appropriately.



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57	Pages 216 through 221, Tables 5-2 and 5-3	Table 5-2 and 5-3 should show the actual screening values that were used for each compound in the SLERA. As noted in the general comments, appropriately conservative values should be used.	There are thousands of TRVs, EPCs, and HQs that would have to be succinctly incorporated into a summary table. The details of the SLERA are provided in Appendix A, and the EPCs, TRVs, and HQs for all COIs and LOEs evaluated in the SLERA are presented in Appendix A, Attachment A2. It should be noted that more than 13,000 cells are populated throughout all of the tables in Attachment A2. Due to the vast amount of data presented in these tables, it is not practical to include them as tables in the main text, other than as summary tables.	EPA fails to see how the Xs in the table cannot be replaced with either the screening value, or more appropriately after further consideration of the comment, the HI associated with each compound and receptor. This will provide a summary table within the text that clearly shows the magnitude of the HI for each compound and receptor.
58	Page 227, Section 6.1.1, first paragraph, first sentence	The text states that a benthic survey was conducted at 97 locations. Page 257 of the document states that 98 locations were surveyed. Please revise, as appropriate.	Comment can be incorporated into revised document. Community data are available from 97 locations and chemistry and toxicity data from 98. Full SQT was therefore not conducted at 1 of 98 sampling locations from fall 2009 survey.	Acceptable.
59	Page 227, Section 6.1.1	Kick net data should be included and discussed in this section, at least qualitatively.	Comment can be incorporated into revised document.  These few locations differ significantly from the remainder of the LPRSA dataset and so will not be used for risk conclusions; they can, however, provide information about sampling uncertainties and error.  Information will be included and discussed in the revised BERA.	The response of incorporating data, at least qualitatively, is acceptable. Note that “sampling uncertainties” may not be fully accurate. Different sampling methods favor or are biased towards collection of different types of organisms, and this is not necessarily linked to uncertainty. In addition, the footnote states that these locations were excluded from analysis due to different collection methodologies, whereas the CPG’s response states they were excluded because they differed significantly from the rest of the LPRSA. This should be clarified and additional justification for exclusion should be provided.
60	Page 233, Section 6.1.3	Support for the approach used to identify and eliminate “outliers” from the reference area datasets should be expanded and revised. As currently written, it appears that any reference area associated with unacceptable results (e.g., toxicity, chemistry) is simply eliminated from the reference area dataset. Clarification is needed, especially regarding the method used to identify outliers.	Locations were identified as outliers if data from those locations exceeded the 3xIQR threshold beyond the 25 <sup>th</sup> or 75 <sup>th</sup> percentile value (as applicable) for either toxicity test data or benthic community data. This analysis was not done for chemistry data at those locations. If a location was identified as an outlier, it was removed from the analysis for all endpoints (i.e., each LOE and the WOE).	EPA supports using 1.5 x IQR as an outlier test. However, the use of an outlier test is no longer needed based on the use of benchmarks to censor the reference data sets.
61	Page 243, Table 6-9 and Section 6.1.3.2	It appears from Table 6-9 that the LPRSA is more contaminated than all reference areas based on all benthic metrics except for Pielou’s J', but this is not indicated in the text. Out of 32 measurements, only 7 are similar to LPRSA. The text, graphs, and figures should present consistent information, and discussion of benthic metrics that show significant difference between LPRSA and reference areas should be added to this section.	CPG fails to see the point of this comment, given that the primary purpose of the benthic community LOE is to discern location-by-location instances of deviation from reference conditions. The salinity zone-based comparisons to reference area conditions (Table 6-9) are not on a location-by-location basis; rather, they show a general trend in the data. As such, the results are not useful for making risk management decisions, which should ultimately be location specific.  Currently, summary text is provided in the BERA (Section 6.1.3.2) regarding significant differences between the distributions of benthic metrics in the LPRSA and reference areas. As per recent discussions with Region 2, both the Mann-Whitney U and location-by-location WOE results will be provided and discussed in the risk characterization section. If deemed necessary, additional discussion regarding the use of Mann-Whitney U test results for risk characterization may be presented in the uncertainty discussion.	The point of this comment is that there are biological differences in the benthic metrics that were evaluated but they are not being acknowledged as evidence that the benthic community of the Passaic River is not as robust as the reference area benthic communities. The comment stands as originally submitted. The CPG must make the changes as directed by EPA.
62	Page 253, Section 6.1.3.3, first paragraph	The use of a minimum reference value is not appropriate for determining similarity between site and reference areas. Such comparisons should be supported by more rigorous statistical analyses and should not be based on overlapping ranges or comparison of minimum values. Also, the statistical comparison of the six metrics show that only 7 measurements, out of 32, are similar to the LPRSA. This is the information that should be summarized. Delete all references to the minimum reference value.	CPG disagrees with Region 2’s position. Specifically, CPG maintains that the minimum reference value, after pre-screening data for extreme outliers, represents a reasonable lower bound that incorporates the variability inherent in natural conditions. Further screening of the dataset (e.g., specifically eliminating toxicity test response data in the reference dataset following removal of outliers) results in an unreasonably inappropriate view of true reference conditions.  As noted (response to Comment No. 61), Mann-Whitney U results associated with Table 6-9 are already discussed at length in the BERA (Section 6.1.3.2) and need not be described in further detail.	EPA does not agree with the response. This issue will be discussed further as the benthic analysis plan is developed.

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63	Pages 257 to 281, Section 6.2	Statistical summaries of the sediment toxicity data collected for the LPRSA and Jamaica Bay, Mullica, and Dundee Dam (e.g., mean, SD, minimum, maximum, 5 <sup>th</sup> percentile, 10 <sup>th</sup> percentile, 25 <sup>th</sup> percentile, 50 <sup>th</sup> percentile, 75 <sup>th</sup> percentile, 90 <sup>th</sup> percentile, and 95 <sup>th</sup> percentile) need to be developed and presented (e.g., in Appendix B).	CPG fails to see the relevance of providing this level of statistical detail, but additional statistics will be provided in the revised document.	Acceptable.
64	Page 257, Section 6.2	Section 6.2 indicates that there are no toxicity data available for the freshwater portion of the Mullica River. Recent samples collected as part of the background/reference data set for Berry's Creek included freshwater toxicity data from the Mullica River. This information should be part of the NOAA database, and it should be included. If it is not available, EPA will provide. Additionally, all of the toxicity data should also be compared to the control data as per previous agreement with EPA.	<p>In this comment, Region 2 provides inaccurate information. Region 2, in recent discussions, made it clear that it has no Berry's Creek data for the freshwater Mullica River dataset. Therefore, this comment was made in error. It cannot and will not be addressed in the revised BERA.</p> <p>Furthermore, CPG disagrees with Region 2's request to compare data to relevant toxicity control data. The purpose of negative control results is purely for quality control of toxicity testing and should not be considered as relevant for making risk management decisions. It should suffice to say that quality control measures were taken, and that batch-specific negative control treatments were performed adequately. Only reference area data are relevant for appropriately assessing risk and for informing management decisions.</p>	EPA recently learned that data from the Mullica River is not available from Berry's Creek; thus, this part of the comment can be ignored. However, as per the PFD and Table 5.2 of the BERA, toxicity data must be evaluated using "LPRSA sediment compared with control and reference information." Therefore, the CPG must make the changes as directed by EPA.
65a	Pages 261-276, Section 6.2, Table 6-12, Table 6-16	The minimum survival and biomass for <i>C. dilutus</i> in the LPRSA are shown on Table 6-12 to be 16% and 5%, respectively (both control-normalized). Table 6-16 show minimum survival and biomass for <i>C. dilutus</i> for the reference area above Dundee Dam to be 71% and 64%, respectively. These results are strikingly different, yet the draft BERA reaches the conclusion of no significant difference for survival and significant difference for biomass, based on statistical analyses. Regardless of statistical differences, there can be no doubt that 16% survival is biologically significantly different from 71% survival. The summary of results (Section 6.2.3.3) fails to recognize the substantial differences in test results that are likely biologically significant, and fails to discuss the locations and sediment chemistry associated with poor test results. Just because toxicity may be localized does not mean it should be ignored.	CPG disagrees that localized toxicity is not discussed. In fact, such impacts are clearly outlined in Section 6.4.3.	Unacceptable. The response fails to address the point of significant differences between site and reference area data. Furthermore, Section 6.4.3 does not adequately address these drastic differences. While differences are identified in Section 6.4.3, they are presented as the result of "urban stress" or proximity to Dundee Dam. The differences should be addressed with more rigor and scientific evaluation. The CPG must make the changes as directed by EPA.

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65b	Pages 261-276, Section 6.2, Table 6-12, Table 6-16	<p>The draft BERA consistently minimizes localized risk (which may be important for minimally mobile receptors and possibly for identifying contaminant source areas), as shown in the following example from Section 6.2.4, page 280, second paragraph:</p> <p><i>“There is limited risk to the benthic community in the estuarine portion of the LPRSA based on a comparison of LPRSA toxicity test data to the reference datasets. Locations with sediment toxicity outside the reference datasets were highly localized (Figures 6-11 through 6-14) and not representative of the entire LPRSA.”</i></p> <p>Finally, <i>C. dilutus</i> biomass, which is one of the two most significant toxicity test endpoints and the one with the greatest predictive power (43.5%), is stated in multiple locations in the draft BERA to be highly uncertain, and therefore the results of this important test are relegated to meaningless status. This endpoint should be incorporated into the evaluation.</p>	<p>CPG disagrees that localized risk is inappropriately minimized in the BERA. The risk assessment for benthic invertebrates is based on a location-by-location analysis and as such, does not truly minimize localized risk. For example, Section 6.4.3 summarizes the results of the WOE analysis, detailing each location for which there was a low or moderate likelihood of impacts. Instances in which localized risk was described (as Region 2 cites in the comment) are intended to show that risk management decisions should not be made on a site-wide basis, but rather targeted where risk is elevated.</p> <p>CPG disagrees that the <i>C. dilutus</i> biomass toxicity test endpoint is “one of the two most significant toxicity test endpoints.” As described in the BERA, the <i>C. dilutus</i> biomass endpoint is highly uncertain due to analytical issues, so the weight given to the endpoint for characterizing risk was low. This was appropriate. Still, CPG also disagrees that <i>C. dilutus</i> biomass was “relegated to meaningless status,” specifically because it was given weight and considered in the WOE analysis. The weighting was specifically assigned to all endpoints so that <i>C. dilutus</i> biomass data could not, by themselves, result in a conclusion of impact, whereas in combination with other variables, it contributed to the conclusion of risk. Given the very low correlation between <i>C. dilutus</i> biomass test results and chemical concentrations in co-located sediment (Appendix B, Table-B1), there appears to be little relationship between <i>C. dilutus</i> biomass and sediment chemistry. Therefore, CPG’s WOE approach in the BERA is conservative.</p> <p>CPG notes Comment No. 71, in which Region 2 clearly states that the predictive power calculation for toxicity tests was “invalid.” In this comment (65b), Region 2 uses the same data to validate their own claim that the <i>C. dilutus</i> endpoint is disproportionately important to other toxicity endpoints. This is therefore a conflicting and inconsistent comment.</p>	The CPG must follow the SQT plan provided by EPA.
66	Pages 261-262, Section 6.2.2 and Table 6-12	<p>Sediment toxicity test results are summarized here, with minimum, mean, and maximum statistics presented after control normalization. Very large differences between the minimum and maximum values are apparent (e.g., 3%-96% and 7%- 98%), suggesting that the mean values mask the high variability in test results. Given that test organisms represent BMI with minimal mobility, it would be much more informative and meaningful to present sediment toxicity data on a point-by-point basis (i.e., present test results by location, not just by minimum, mean, and maximum calculated for the LPRSA). This preferred approach would allow for risk evaluation on a scale relevant to BMI.</p>	<p>Location-specific sediment toxicity data is provided in the data report and in Appendices B and K. Tables 6-12 through 6-14 are meant to summarize that data briefly rather than provide exhaustive (and redundant) data tables.</p> <p>In addition, the SLERA provides a comparison to thresholds for the sediment chemistry.</p>	The appendices and tables identified in the response are not adequate to address the issue in the original comment; thus, additional text must be added.

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67	Page 262, Table 6-12	The <i>Ampelisca</i> tests were not run appropriately (renewal vs. static). This needs to be discussed in this section.	<p>The CPG strongly objects to and disagrees with this comment; this is an example of Region 2 and its Partner Agencies' reviewer's unfamiliarity with the Region 2-approved QAPPs and SOPs for this work. Moreover, this is direct evidence that Region 2 is not providing an appropriate level of oversight and quality control in preparing Agency comments. The <i>Ampelisca</i> test was conducted according to the Regions 2-approved QAPP (Windward 2009b), which included the project-specific <i>Ampelisca</i> sediment toxicity test SOP that was reviewed by Region 2. Region 2's contractor provided comments on the draft SOP on November 19, 2009, specifying that the method be conducted as a static renewal test; the SOP was revised accordingly. In addition, the Region 2 lab that conducted the split sample analysis followed the same protocol.</p> <p>This comment directs CPG to take an approach inconsistent with a Region 2-approved QAPP (Windward 2009b) and the Sediment Toxicity Data Report (most recently submitted to EPA January 2012) (Windward 2012d). In addition, this comment is inconsistent with EPA's own laboratory protocol for the same exact test.</p> <p>See the Region 2-approved QAPP for Surface Sediment Chemical Analyses and Benthic Invertebrate Toxicity and Bioaccumulation Testing (finalized October 8, 2009), and see Section 5.3.4 of the SOP modified for consistency with EPA comments for Acute Toxicity of Sediments to the Marine Amphipod, <i>Ampelisca abdita</i>.</p> <p>No change will be made in the revised BERA.</p>	EPA agrees that the original comment was not worded clearly. However, as we have discussed, even though the modification was approved prior to conducting the test, the <i>Ampelisca</i> test method used was modified from the normal parameters associated with the test. EPA is asking for a discussion on how the use of a renewal test vs. a static test could influence the results of the toxicity tests. This discussion must be included in the BERA.
68	Page 262, Section 6.2.3	Results need to be compared with control data, and the report needs to acknowledge that reference areas "still contain contaminants" even if they are not site-related. This is important for understanding effects data and is the main reason the control data is utilized.	CPG disagrees with this comment. Specifically, the main reason that control data is utilized is for the purpose of laboratory QA/QC, to ensure that the test organisms are healthy and can survive (and grow, etc.) under the imposed exposure conditions. This is the basis for causal experimentation. The purpose of the negative control is not to provide a baseline for comparison for site data in the risk characterization. Therefore, such a comparison should not be included in the risk assessment. It should suffice to say that standard QA/QC measures were taken during laboratory testing and that negative control treatments met established criteria for test acceptability.	As per the PFD and table 5.2 of the BERA, toxicity data must be evaluated using "LPRSA sediment compared with control and reference information." Therefore, the CPG needs to make the change as directed by EPA.
69	Pages 264-265, Section 6.2.3.2 and Table 6-15	This section should be called "Comparison with control and reference data" and Table 6-15 should have control data columns.	See above response (Comment No. 68).	As per the PFD and table 5.2 of the BERA, toxicity data must be evaluated using "LPRSA sediment compared with control and reference information." Therefore, the CPG needs to make the change as directed by EPA.
70	Pages 275-277, Section 6.2.3.3	A summary of results cannot be completed without a robust discussion of how the data compare with the control data, and the summary is biased without the inclusion of control and Mullica River data. Please revise this section after adding the control data and Mullica River data to the report.	See above response (Comment No. 68). Control data will be discussed in the revised document as appropriate, but will not be used for making risk conclusions. Similarly, the use of reference data from a rural location (rather than an urban reference area as approved by Region 2) would bias the analysis and create confusion regarding the purpose of the risk assessment and future remediation actions. Specifically, the rural condition incorporates both impacts of an urbanized setting and those associated with sediment contamination. The use of an urban reference condition incorporates the former impact but excludes the latter, thereby focusing the characterization of risk on the effect of contaminants. This is far more appropriate for informing remediation options.	As per the PFD and table 5.2 of the BERA, toxicity data must be evaluated using "LPRSA sediment compared with control and reference information." Therefore, the CPG must make the change as directed by EPA.

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71	Pages 281-307, Sections 6.3-6.4.3	<p>These sections contain many erroneous assumptions and calculations and invalid comparisons. The methods used in the line of evidence for sediment, which are further used to support the weight of evidence for the sediment quality triad, are not acceptable. These sections need to be completely revised following an acceptable approach (EPA will provide an example soon). For example, a minimum reference value is used inappropriately, invalid reliability analyses are conducted, and inappropriate weighting of sediment metrics is used.</p>	<p>The CPG vehemently disagrees with this statement. The CPG provided the draft RARC Plan (Windward and AECOM 2013) to Region 2 well in advance of submitting the BERA, including methods and all analyses to be performed. Region 2 provided no comments at the time that the RARC Plan was submitted that would suggest that Region 2 disagreed with the proposed risk assessment methodologies.</p> <p>The statement that assumptions and calculations are erroneous is not supported with any information or analysis. Region 2 must provide evidence to support such a claim. Invalid comparisons are discussed in comments above regarding the use of the minimum reference value and negative control data. Region 2 has provided no reason why the reliability analysis is invalid; simply that it is. At the same time, Region 2 has used that same analysis to validate their claim that the <i>C. dilutus</i> biomass endpoint is “significant” (see Comment No. 65a). Thus, Region 2’s line of reasoning is inconsistent.</p> <p>Inappropriate weighting is discussed in Comment No. 65b. The weighting of the sediment chemistry LOE was given a lower weight due to the fact that sediment chemistry is not clearly related to measurable toxicity in LPRSA sediments. The use of screening criteria as a means for evaluating chemistry in the BERA is inappropriate; this was done in the SLERA (Appendix A to the BERA). Screening criteria are correlation-based rather than based on causative experimentation, so criteria are inherently uncertain when predicting toxicity in the laboratory or field. Furthermore, confounding variables in the LPRSA exist throughout the site including, but not limited to, high organic loading, historic habitat alteration and degradation (e.g., channelization and dredging), urban runoff, and deposition of rubbish. These concepts are laid out and detailed extensively in the PFD and the BERA (Section 2).</p>	<p>The CPG must follow the SQT plan provided by EPA (previously provided, attached for reference).</p>

No.	Section	EPA Specific Comment Submitted 5/1/2015	CPG RTC Submitted 9/10/2015 or 9/15/2015	EPA Response to CPG RTC
72	Page 281, Section 6.3	<p>The text states: "...relying solely on NJDEP ESCs for an estimate of benthic risk in the LPRSA is overly protective, given that direct measures of effect (i.e., toxicity, benthic community metrics) are available.... The reliability of the NJDEP ESC values in predicting site-specific toxicity of LPRSA sediment (relative to reference area data) was analyzed."</p> <p>Please note that, with the notable exception of the screening value provided for 2,3,7,8-TCDD, the NJDEP ESCs are <i>screening levels</i> used to identify the potential for risk and the need for further evaluation using more rigorous, site-specific evaluations. However, the selected "direct measures of effect" should be conducted in accordance to approved methods and within the correct context for the study.</p> <p>The 2,3,7,8-TCDD ESC developed by the USFWS (Kubiak et al., 2007) is given greater weight due to its derivation using site-specific, chemical-receptor paired information from the Newark Bay Complex.</p> <p>Finally, with the exception of 2,3,7,8-TCDD, the ESCs were never intended to be site-specific. Additional comments on the use of NJDEP ESCs are provided in relation to Appendix A.</p>	<p>No change will be made to the revised BERA.</p> <p>This comment is addressed below in comments on Appendix A (see response to Comment No. 156c). The CPG agree that the NJDEP ESCs are screening levels that are only appropriate for use in a SLERA, assuming that the screening level is in itself valid (e.g., relevant to a given receptor group and based on good science).</p> <p>As discussed in Appendix D.1 of CPG's comments on Region 2's 2014 FFS, the 2,3,7,8-TCDD value derived from Kubiak et al. (2007) is an inappropriate and indefensible ecological toxicity threshold based on the results of a non-peer-reviewed analysis (i.e., a conference presentation). The sediment threshold for 2,3,7,8-TCDD was derived by USFWS by poorly pairing the two tissue values for transplanted oysters reported in Wintermyer and Cooper (2003) (one from Arthur Kill and the other from Sandy Hook) with sediment data collected for another study—the Contaminant Assessment and Reduction Program (CARP)—to establish a cause and effect relationship.</p> <p>The sediment threshold was back calculated by Kubiak et al. (2007) from the tissue concentrations by applying a biota-sediment accumulation factor (BSAF) that was calculated using only those same two tissue concentrations. BSAFs were calculated contrary to EPA methodology and guidelines for developing BSAFs (Burkhard 2009), which stress the importance of using data with similar underlying conditions (both ecological and chemical). According to EPA, "mixing of Csoc-CI (sediment and tissue) paired observations with different underlying conditions is not recommended and will, in all likelihood, result in BSAFs with poor predictive accuracy." Judd et al. (2013) evaluated a large BSAF dataset from EPA's Mid-Continent Ecology Division and demonstrated that biota-sediment relationships cannot be assumed to be linear, and that basing decisions on BSAFs focused on one chemical is highly uncertain. The use of only two paired observations to develop a sediment benchmark (and ultimately a cleanup goal) for a single chemical is not defensible.</p> <p>Clearly, in addition to the tissue thresholds being inappropriate for use as effect and no-effect thresholds (see TRV tables attached), the methods used by USFWS in the back calculation misapplied the available data (i.e., used tissue and sediment data collected independently [i.e., not co-located] and for other purposes and combining them as pairs to calculate BSAFs). A single sediment sample collected from Arthur Kill was paired with one tissue sample result (n = 1) from a single location an unknown distance from where oysters were exposed (Wintermyer and Cooper 2003) to derive a BSAF. The sediment was not co-located with the tissue data and was from one sediment sample, failing to provide an indication of the variability in chemical concentrations. It appears a BSAF was also calculated for Sandy Hook, but the location of the "co-located "sediment used to derive this BSAF is not even provided.</p> <p>Interestingly, the sediment PRG for 2,3,7,8-TCDD that is intended to provide a protective level for invertebrates affected adversely by sediment concentrations derived from this calculation (3 ppt dw) is similar to the background values reported from Mullica River/Great Bay, an area considered by Region 2 to represent rural background conditions. This would therefore indicate that the concentrations of 2,3,7,8-TCDD found in rural estuarine locations in New Jersey would result in reproductive failure in oysters. The presence of robust oyster beds in New Jersey estuarine waters demonstrates this is not the case.</p>	<p>Uncertainty is inherent in all ESCs (or ESLs) and TRVs. At the SLERA stage of the ERA process, selected ESCs should be conservative and where data allow, should be based on NOAELs or No Effect Concentrations, per ERAGs guidance. These values are to be replaced in the BERA with appropriate TRVs. It is agreed that there would be greater confidence in the threshold derived by Kubiak et al. (2007) if it was based on co-located sediment and tissue samples. However, and given these recognized uncertainties, this value is considered one of several that can be used in the BERA, especially since it is based on data from Newark Bay. Therefore, EPA disagrees with the CPG assertion that the 2,3,7,8-TCDD value derived from Kubiak et al (2007) is inappropriate, and EPA expects this value to be used in the BERA.</p>

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73	Page 293, Section 6.3.2.4, last bullet	<p>The text references Appendix M of the draft BERA to aid in the justification of the CPG's opinion that benthic life is limited to the top 2 cm of the sediment bed. Review of Appendix M indicates that burrows or tube lengths for a large number of organisms that inhabit the LPRSA, including those most commonly found (polychaete and oligochaete worms), are characterized as deep, moderately deep, or very deep. The text also references the Germano &amp; Associates 2005 report, but provides no further detail as to what conclusions were drawn from that investigation regarding burrowing depths.</p> <p>Therefore, the conclusion that benthic life is limited to the top few cm of sediment is not supported by the evidence provided. The entire document needs to be revised accordingly.</p>	<p>The conclusions drawn from the literature regarding benthic invertebrate burrowing depths are based on aquatic systems other than the Lower Passaic River. No reports, other than the Germano &amp; Associates (2005) SPI survey, have discussed burrowing depth within the 17-mi study area. The differences in observations among the published literature and those of Germano &amp; Associates (2005) are striking. Germano &amp; Associates (2005) observed limited burrowing activity below the aRPD boundary (approximately 2 cm depth) and identified multiple factors for their observations, including physical disturbance of the sediment near the mouth of the Passaic River and indications that sediment in the LPRSA has a high organic load, which acts to restrict burrowing depth. Further, the current BERA text does not claim that benthic life is limited to the top few centimeters; rather, that the site-specific empirical evidence indicates that the majority of the benthic community resides above the aRPD boundary. Text in the BERA will be expanded to cover all the LOEs that support the fact that the majority of the biological activity in LPRSA sediment is restricted to those aerobic sediments above the aRPD boundary.</p> <p>The CPG requests that Region 2 provide citations that a significant amount of the benthic invertebrate biomass in the LPRSA is found deeper than 2 cm.</p>	Please see EPA Response to Comment No. 27.
74	Page 307, Section 6.4.3, last bullet	Please remove this bullet. This conclusion is beyond the scope of this document and is not appropriate.	The CPG disagrees with this comment. The relevant scientific literature on urban rivers and the relevant site-specific data point to this conclusion. The CPG asks that Region 2 provide the facts and data to support removing this bullet.	Given that one of the potential remedies would be dredging and backfilling with clean material or installing a cap system, there is a high probability that post-remediation conditions could support a different benthic invertebrate community. EPA stands by its comment to remove this bullet. The CPG must make the change as directed by EPA.
75	Pages 310-311, Table 6-27	The UCLs presented for dieldrin and hexachlorbenzene are lower than the means. Please revise, as appropriate. In addition, the table should include a footnote stating how non-detects are handled.	<p>Means are based on detected values only. UCLs are based on ProUCL-recommended UCLs, including both detected and non-detected values (latter includes imputed values that are not reflected in the summarized means, which accounts for why UCLs are lower than mean values reported in table).</p> <p>Footnotes will be added to summary tables to clarify in the revised BERA.</p>	Acceptable.
76	Pages 315-318, Table 6-28	<p>There are two additional sources that should be added to Table 6-28 (2,3,7,8-TCDD estuarine):</p> <p>Wintermyer, M.L. and Cooper, K.R. 2003. Dioxin/furan and polychlorinated biphenyl concentrations in eastern oyster (<i>Crassostrea virginica</i>, Gemlin) tissues and the effects on egg fertilization and development. Journal of Shellfish Research 22 (3):737-746.</p> <p>Wintermyer, M.L. and Cooper, K.R. 2007. The development of an aquatic bivalve model: Evaluating the toxic effects on gametogenesis following 2,3,7,8-tetrachlorodibenzo-<i>p</i>-dioxin (2,3,7,8-TCDD) exposure in the eastern oyster (<i>Crassostrea virginica</i>). Aquatic Toxicology 81 (1):10-26.</p> <p>In addition, the following should be added as a freshwater TRV source:</p> <p>Chen, J. 2014. Cardiac toxicity by sublethal 2,3,7,8-tetrachlorodibenzo-<i>p</i>-dioxin correlates with its anti-proliferation effect on cardiomyocytes in zebrafish embryos. Environmental Toxicology and Chemistry DOI 10.1002/etc.2822.</p>	As discussed in Appendix D.1 of CPG's comments to Region 2's 2014 FFS, the 2,3,7,8-TCDD value derived from Wintermyer and Cooper (2003) is an inappropriate and indefensible ecological toxicity threshold. The evaluation of this paper is included in the attached TRV tables. The other studies do not meet acceptability criteria (injection studies and inappropriate endpoint).	EPA disagrees that these sources are inappropriate. EPA expects these sources to be used in the BERA. The CPG must make the changes as directed by EPA.
77	Page 328, Section 6.5.3.2, first sentence below figure	If no estuarine values are available, use freshwater as a surrogate and discuss in uncertainty section.	The use of freshwater values as a surrogate for toxicity data to evaluate estuarine water data will be included and presented in the uncertainty section of the revised BERA.	Acceptable.

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78	Pages 330-331, Section 6.5.4.1 and Table 6-29	The report should discuss all surface water, not just near-bottom surface water. In Table 6-29, please include a comparison of freshwater and estuarine concentrations. Fresh water values should be used if estuarine do not exist.	<p>This comment directs CPG to take an approach inconsistent with previous agreements and documentation .Comment is inconsistent with Table 2-2 of the RARC Plan (Windward and AECOM 2013), which was revised to reflect Region 2's comment and limit the surface water evaluation for benthos to near bottom water samples. The RARC Plan and Appendices were submitted to Region 2 on April 16, 2010, and revised drafts were submitted on February 10, 2011; August 9, 2011; April 13, 20102; and October 29, 2013. Region 2 commented on the document drafts; comments were received on September 10, 2010; November 5, 2010; July 11, 2011; February 6, 2012; August 30, 2012, and January 31, 2014.</p> <p>Region 2's September 10, 2010, comment on the RARC Plan (EPA 2010) stated that benthos should be evaluated with surface water "immediately above the sediment, from 0-6 inches." The following RARC Plan text (submitted on February 10, 2011) was revised accordingly to state this.</p> <p>No changes to the revised BERA will be made. This section is the benthic receptors section and per the PFD, benthic receptors are only screened against near-bottom water quality data. Other receptors are screened against other water quality data.</p>	The CPG misunderstands the comment. The comment is asking for a discussion of all the surface water that was collected. A qualitative discussion comparing the concentration of compounds in near-bottom surface water and surface water should be included so that the reader can determine if the concentration of the most frequently detected compounds is similar throughout the water column or is generally higher or lower in the surface water compared to the near-bottom surface water.
79	Page 332, Figure 6-31	Please clarify why no data above River Mile 12 are shown and revise as appropriate.	Region 2 and its reviewers should be aware that no surface water data were collected above RM 10.2 other than background samples above Dundee Dam consistent with Region 2-approved surface water QAPPs. Text can be added to the revised BERA to reiterate this for Region 2's benefit.	Acceptable.
80	Page 338, Section 6.6.1	Organic compounds and the bioaccumulation test results should be included in this section. Many more compounds than those listed here should be carried through for this evaluation. Please refer to specific comments on the SLERA and make the necessary revisions throughout the document.	<p>See specific responses to SLERA comments.</p> <p>Please note that the bioaccumulation tissue (for worms) was evaluated as part of the benthic tissue LOE. Any compounds that were evaluated will be discussed in the BERA.</p> <p>If a compound is detected in tissue and comes through the SLERA as a COPEC, then it will be discussed.</p>	Acceptable.
81	Page 347, Figure 6-36	A similar figure for comparison to control data should be included.	Comment can be incorporated into revised document	Acceptable.
82	Page 350, Table 6-35	This table is more appropriate for the FS and should not be included in the BERA. Please delete the table and associated text.	CPG disagrees that a summary table identifying key COPECs as COCs should be eliminated from the revised BERA. The table and text present a summary of all the results. It is appropriate to provide a summary of the results in a BERA and provide a synopsis in the text. Table 6-35 is the summary of the BERA; text will not be deleted.	The identification of final COCs is often reserved for the FS, but risk drivers (i.e., those COPECs contributing most to risk) can be identified in the BERA as "preliminary COCs" or "risk drivers."
83	Pages 351-441, Section 7	Section 7 in its entirety is incomplete and unacceptable because tissue data for all fish species collected are not presented and evaluated (e.g., carp). Regardless of whether a particular species is selected as a focal species, all tissue data need to be presented and discussed. The list of COPECs must be revised based on comments on the SLERA. The SETAC reference provided is fine for the uncertainty section, but it does not supersede EPA guidance. Whole body tissue concentrations should be screened for all compounds.	<p>See response to Comment No. 3 and specific SLERA comment responses.</p> <p>The CPG disagrees that whole-body fish tissue should be screened for all compounds. Per the RARC, metals and PAHs will be evaluated using the dietary approach in the revised BERA.</p>	Measured concentrations of COPECs in fish tissue, with the exception of PAHs due to the expectation of metabolism in vertebrates, should be compared to (chemical-specific, species-specific and tissue type-specific) residue-based TRVs in the BERA, (e.g., Low Effects residue-based TRVs provided by the USACE ERED database). Additional comparisons of estimated dietary doses for metals and PAHs to dietary or dose-based low effect TRVs will be evaluated in the BERA. For the SLERA, measured concentrations for all compounds in fish tissue should be compared to residue-based TRVs associated with NOAELs.
84	Page 351, Section 7, last paragraph, fourth sentence	The text states that freshwater benthic omnivorous fish were found in limited numbers. This statement conflicts with information presented in Section 2: " <i>Large numbers of carp were caught (215 carp, 4.8% of fish caught) between RM 4 and RM 17.4 during the LPRSA fish surveys (Section 2.3).</i> " Please revise the text for consistency.	Comment can be incorporated into revised document.	Acceptable.



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85	Page 353, Section 7.1.1, second sentence	The text states that "Fish tissue COIs included only organic chemicals (other than PAHs)". PAH data are available and should be used. Please revise this section accordingly.	The CPG disagrees that whole-body fish tissue should be screened for PAHs. Per the RARC, metals and PAHs will be evaluated using the dietary approach in the revised BERA.	Please see response to Comment No. 83.
86	Pages 354-355, Table 7-3, and Pages 357-358, Table 7-5	These tables include non-target species (e.g., white catfish, white sucker, smallmouth bass, and northern pike), but exclude carp. Carp should be included.	See response to Comment No. 3. Carp were not included as representative fish in the Region 2-approved PFD.	See EPA response to Comment No. 3 as well as other relevant comments. Carp must be included in these tables.
87	Page 357, Section 7.1.2	The discussion needs to include more detail on the endpoints plotted on the species sensitivity distributions. Given that some endpoints have a greater affinity for adverse biological impacts, this information needs to be provided to ensure that a protective TRV is established.	Comment can be incorporated into revised document.	Acceptable.
88	Page 359, Table 7-6	The ACRs referenced as EPA values were derived for surface water, not tissue. There is no evidence that ACRs derived from surface water toxicity testing are applicable to fish tissue TRV derivation. Use of surface water ACRs is inappropriate for fish tissue TRV derivation. An alternate approach might include accessing the USACE ERED database, which presents acute and chronic toxicity data based on tissue residue (whole body, by organ, fillet, etc.) for multiple fish species. For example, the USACE ERED database (Matta et al. 2001) shows that mummichog exposed to MeHg had an LD43 (whole body, mortality endpoint) of 0.46 mg/kg ww. This value can be considered a severe effect endpoint from which a chronic value can be estimated. Even if a conservative ACR such as 3 is applied (as opposed to the more often recommended ACR of 10 for estimating chronic values from acute values), the whole body chronic or estimated low effect value would be around 0.15 mg/kg MeHg, ww.	The ACRs were based on a large number of studies evaluated by EPA reflecting the chemical modes of action. Such a synthesis is not available for tissue residue effects data. Toxicity, as measured by aquatic and tissue residue effects levels, acts via the same mode of action. Given the relative paucity of data for tissue-based ACRs, their uncertainty is greater. We acknowledge that tissue effects thresholds may not be directly proportional to aquatic effects thresholds, thus ACRs could differ to some degree. This uncertainty will be evaluated in the revised BERA.	Acceptable.
89	Page 361, Section 7.1.3.1, 5 <sup>th</sup> bullet	<p>The stated emphasis on "population-level" risks is noted. However, sublethal impacts on individuals may translate to significant population impacts. Missing from the existing presentation is the important role chemical exposures are known to exert on receptor increased vulnerability to adverse health outcomes in growth, survival, reproduction and disease.</p> <p>Through other studies, several of the key contaminants of concern in the LPRSA have been shown to increase receptor vulnerability to disease and decreased adaption to other stressors in their habitat, (see <a href="http://www.epa.gov/ncer/science/endocrine/researchproj.html">http://www.epa.gov/ncer/science/endocrine/researchproj.html</a> ).</p> <p>At a minimum, this concern should be incorporated into the Uncertainty Section.</p>	As long as there is a valid linkage of these alternate endpoints to documented effects on growth, reproduction, and survival, they are considered and discussed. This was presented in the TRV document given to Region 2 in 2011. Alternative endpoints (with no established link to growth, reproduction, or survival) are not the subject of this BERA.	It is agreed that preferred endpoints for TRVs are survival, growth, and reproduction. Some sublethal endpoints such as endocrine disruption (which can result in alteration of sex characteristics) clearly can result in adverse reproductive effects and ultimately in population level impacts. Support for the applicability of TRVs based on endocrine-related effects can be found in many of the commonly accepted TRVs related to dioxin or PCB exposures, where "dioxin-like effects" are based on AHR-associated effects. Most avian TRVs for dioxins and PCBs are, for example, based on AHR-associated endpoints. While these endpoints are not the only endpoints of concern, they are important to consider and include in the selection of TRVs.
90	Page 362, Table 7-7	The table lists NOAELs as "not applicable." This is not true, they are applicable and should be included.	For the use of SSDs, only LOAELs were evaluated; the 5 <sup>th</sup> percentile LOAEL was selected, so "na" is the appropriate term. Only SSDs of known, measured adverse effects were evaluated.	NOAELs should still be reported in the table so that the reader can distinguish the concentration gap between NOAELs and LOAELs.

No.	Section	EPA Specific Comment Submitted 5/1/2015	CPG RTC Submitted 9/10/2015 or 9/15/2015	EPA Response to CPG RTC
91	Page 363, Figure 7-1	<p>This and other similar figures are unclear and need to be revised. The tissue TRV for MeHg is stated to be 0.37 mg/kg (dotted vertical line), based on the 5th percentile of the SSD. The species-specific points on the curve seem to align with the LOAELs discussed in the text, but it is unclear whether these LOAELs are based on acute or chronic exposures.</p> <p>Furthermore, it is unclear whether these LOAELs are the result of the (inappropriate) application of the surface water ACR (3.731). This and similar figures should clearly state whether the SSD is based on acute or chronic exposures.</p>	In the revised BERA, the figure will be revised to clarify whether the LOAELs are acute or chronic. See response to Comment NO. 88 for discussion of ACRs.	Acceptable.
92	Page 367, Section 7.1.4.1, first paragraph, first sentence, and Table 7-9	The text states that "In addition to the focal species, HQs were calculated for three additional species for which LPRSA data were available: smallmouth bass, northern pike, white catfish, and white sucker (Table 7-9)." Carp should be included here, and in Table 7-9.	See response to Comment No. 3. Carp were not included as representative fish in the Region 2-approved PFD.	See EPA response to Comment No. 3 as well as other relevant comments. HQs must be presented for carp.
93	Page 371, Table 7-11	Footnote "d" is missing from the table. Please revise.	Footnote "d" was inadvertently omitted and will be replaced.	Acceptable.
94	Page 376, Section 7.2.2.3, last paragraph	The last paragraph on this page should include fish with the worms and crabs.	Commenter is unclear; CPG requests that Region 2 clarify comment.	The comment is pointing out a typo. The text reads "The proportion of worms, blue crab and in the diets..." The paragraph above this one indicates that worms, blue crab and fish were used in the dietary dose equation; thus, the sentence should read "The proportion of worms, blue crab and <b>fish</b> in the diets..."
95	Page 377, Section 7.2.2.3, last paragraph	The exposure of fish species to multiple areas needs to be evaluated and not limited to just the area in which it was captured.	Fish were collected per the data objectives in the QAPP and based on discussions with Region 2 regarding which fish to composite and how many samples to collect. There are not enough species-specific samples to address this comment.	The response appears to miss the point that fish are mobile and location of collection should not preclude other locations as possible exposure locations for fish. For example, just because channel catfish were only collected above RM 8 does not mean that channel catfish cannot be found in other freshwater areas down to the salt wedge. Thus, the exposure area for each receptor should be based upon physical parameters, such as salinity, and not location in which it was captured.
96	Page 377, Section 7.2.2.3, Table 7-15	Mudflats are defined in the document as those areas that are "within - 2 ft MLLW and < 6° slope and include all grain sizes." This definition will include gravel areas as mudflats. As such, mudflats should be characterized 2 ways -- one as described in the document currently and one using fine grains only. This comment also applies to Table 8-5.	<p>The CPG disagrees with this comment, which is based on a false premise and also inconsistent with the Region's 2014 FFS/RI and previous agreements.</p> <p>This definition is consistent with presentations given to Region 2 on March 6, 2014, and Region 2-approved QAPPs. Moreover, the grain size distribution is the same between the FFS/RI mudflats and the BERA mudflats. See Figure 1-a in the October 10, 2009, Benthic QAPP (Windward 2009b) and in both QAPP addenda from 2010 (Windward 2010a, b) as examples. See grain size distribution from the Region 2 FFS (Louis Berger et al. 2014) (same as in the LPRSA mudflats for the BERA). Also see the presentation given to Region 2 by CPG on March 6, 2014.</p> <p>Per discussion with Region 2, descriptive characterization of the mudflats will be added to the revised BERA, but the definition of mudflats will not change.</p>	See CPG response to comment #24, which appears to be inconsistent with this response. The revised document will be reviewed to confirm that EPA's comment has been addressed appropriately.
97	Pages 385 to 386, Table 7-17	This table includes a very short list of COPECs, including no dioxin, PCBs, or pesticides. Please revise, as per other comments.	<p>The limitation of the fish dietary evaluation to just metals and PAHs is consistent with the Region 2-approved PFD (Windward and AECOM 2009) and the RARC Plan (Windward and AECOM 2013).</p> <p>See footnote "e" to PFD Table 5-2 (Windward and AECOM 2009) and the same language in the RARC Plan (Windward and AECOM 2013) under footnote "d" of Table 2-2. The PFD went through multiple rounds of review by Region 2 and was approved on July 31, 2009.</p>	Please see response to Comment No. 83.

No.	Section	EPA Specific Comment Submitted 5/1/2015	CPG RTC Submitted 9/10/2015 or 9/15/2015	EPA Response to CPG RTC
98	Page 387, Table 7-18	<p>The following mean concentrations appear to be incorrect. Please review/revise as noted below:</p> <p>a. Mudflat Areas from LPRSA RM 0 to RM 17.4:</p> <p>- Chromium 120 mg/kg</p> <p>b. LPRSA ≥ RM 6:</p> <p>Chromium 110 mg/kg</p> <p>Copper 130 mg/kg</p> <p>c. LPRSA ≥ RM 8:</p> <p>- Copper 110 mg/kg</p> <p>d. LPRSA RM 0 to RM 17.4</p> <p>Chromium 110 mg/kg</p> <p>Copper 140 mg/kg</p>	<p>Region 2 is requested to provide the calculations for the values presented in this comment. The means presented in Table 7-18 of the draft BERA are consistent with the data statistics presented in BERA data appendices.</p> <p>No change to revised BERA.</p>	<p>The values provided were derived simply by calculating the arithmetic mean of the relevant data in Appendix K, Table K1 of the BERA, and rounding the result to two significant figures. Please refer to the attached spreadsheet, which is a modified version of that table that includes three tabs (Chromium – Mudflats, Chromium by RM, and Copper by RM) in which these calculations were performed. The resulting values can be found at the bottom of each tab. The “Metals” tab is unchanged from what was provided in Appendix K, Table K1. The comparison table in Appendix K, Table K1 (which is retained as the last tab in the attached spreadsheet) also must be revised as the mean chromium and copper concentrations provided in this table are incorrect.</p>
99	Page 388, Table 7-19	<p>Please include all available measured concentrations in fish in this table.</p>	<p>Table 7-19 summarizes the calculated dietary doses for each of the fish species. Therefore, it is not relevant to include the tissue-specific results.</p> <p>No change to revised BERA.</p>	<p>See response to Comment 97. Calculation of dietary doses in the BERA does not preclude the need to present calculations of HQs based on measured concentrations of chemicals in fish tissue to low effects fish tissue-based TRVs.</p>
100	Page 396, Table 7-21	<p>The lists of COPECs in this table are different from Tables 7-8 and 7-9. Please revise for consistency.</p>	<p>Tissue COPECs were evaluated separately from dietary COPECs. These are two separate LOEs. The dietary LOE for fish focused on those COPECs that cannot be reliably assessed through a tissue residue approach.</p> <p>Clarification will be made to the revised BERA.</p>	<p>Acceptable.</p>
101	Page 398, Section 7.2.6, sixth sentence	<p>Clarify which specific USEPA document contains the recommendation for metals being used only for screening purposes.</p>	<p>Comment can be incorporated into revised document. This document is the following: USEPA. 2007. Framework for metals risk assessment. EPA 120/R-07/001. Office of the Science Advisor, Risk Assessment Forum, US Environmental Protection Agency, Washington, DC.</p> <p>As stated in Section 7.2.4.2, USEPA has recommended that this dietary approach for fish be used “only for conservatively screening for exposure and potential risks to consumers (i.e., in cases where whole body residues in prey are below dietary toxic thresholds)” (USEPA 2007b). For more definitive assessments, USEPA suggests that further research is needed to quantify the bioavailability and effects of inorganic dietary metals (USEPA 2007b).</p>	<p>Acceptable.</p>
102	Pages 399-400, Table 7-22	<p>The same COPECs should be evaluated for all media and species.</p>	<p>Per Appendix A of the RARC Plan, “Screening-level values are medium and receptor group specific. The result is a set of COPEC-receptor pairs to be evaluated in the BERA.” Region 2 did not comment on this in its multiple reviews of the RARC Plan and Appendices.</p> <p>As discussed with Region 2 in the May and June 2015 Region 2-CPG teleconference calls, the SLERA will screen by species, but if any chemicals come through for any species in a given media, those chemicals will be evaluated for all species for that media in the BERA.</p>	<p>Acceptable.</p>
103	Pages 402-403, Table 7-23	<p>The table should include a footnote stating how non-detects were incorporated into the mean concentration calculations.</p>	<p>Comment can be incorporated into revised document. Footnotes will be added to summary tables to clarify in the revised BERA.</p>	<p>Acceptable.</p>

No.	Section	EPA Specific Comment Submitted 5/1/2015	CPG RTC Submitted 9/10/2015 or 9/15/2015	EPA Response to CPG RTC
104	Page 405, Table 7-24	While the estuarine TRV for copper in surface water (5.1 µg/L) may be sufficiently protective of fish, the derivation of this TRV is not transparent. This table shows that for copper the BERA uses an ACR of 2 for deriving the chronic surface TRV for protection of fish, based on acute data for 64 invertebrate species and 20 fish species. It is not clear why (1) invertebrate data are included in the dataset, (2) chronic toxicity data for fish are not used directly, and (3) the ACR of 2 is selected, which is lower than most ACRs presented in the large aquatic toxicity database presented in EPA/4405-84-031 (the 1985 water quality criteria document for copper). Similar questions are (to varying degrees) associated with the derivation of other surface water TRVs. Clear explanation or justification is needed.	The CPG disagrees with Region 2's contention that derivation of estuarine surface water is not transparent. Section 2.1.1 of Appendix D details the derivation of the estuarine TRV for copper, including a justification of the ACR.  Additional clarifying text will be added, as appropriate, in the revised BERA.	The revised document will be reviewed to confirm that EPA's comment has been addressed appropriately.
105	Page 417, Section 7.4.2	The text should clarify that contaminant concentrations in adult mummichog used to establish or present egg/adult contaminant relationships are based on whole body fish, and not on fillet or organ-specific samples.	Comment can be incorporated into revised document.	Acceptable.
106	Page 419, Section 7.4.3.1	The TRV for total PCBs in egg tissue (258 ug/kg ww) is approximately five times higher than the total PCB concentration in egg tissue (50.4 ug/kg ww) associated with long-term, apparently multigenerational reproductive effects. The selected TRV is linked to reduced hatchability, while the rejected value (50.4 ug/kg ww, based on a lower dose) is linked to failure to spawn. PCBs are known to contribute to or cause long-term effects in other well-studied receptors (e.g., mink), and rejection of the lower value as an appropriate egg-based TRV is not supported by the information presented. Unless other relevant information suggests otherwise, the 50.4 ug/kg ww value appears to be the most appropriate egg-based TRV for assessing risks to fish. Please revise accordingly.	The CPG disagrees with Region 2's contention. An explanation of why this value (50.4 ug/kg ww) was not used is provided in Section 7.4.3.1. This value is used in the SLERA and the uncertainty and implications of TRVs based on this study will be discussed and revised in the BERA.	The explanation provided is not sufficient to exclude this value. As presented elsewhere in our comments, multiple values can (and should) be used and this value should be included in the BERA.
107	Page 423, Table 7-30	There appears to be a typo in this table; please remove the reference to great blue heron and replace with mummichog.	Comment can be incorporated into revised document.	Acceptable.
108	Page 423, Section 7.4.4.3	Please add the following reference, and details from the study, to this section. A copy of the document has been included. Bugel, S. 2009. An integrated biomarker approach for assessing exposure and effects of endocrine disruptors and other contaminants in killifish ( <i>Fundulus heteroclitus</i> ) from the New York-New Jersey harbor estuary. Rutgers University – Thesis.	This comment directs CPG to take an approach inconsistent with previous agreements and documentation. Moreover, this comment is not an ecological risk-related matter and appears to be related to natural resource damage. The evaluation of biomarkers as an endpoint to be assessed is outside the assessment endpoints of "survival, growth, and reproduction," as specified in the Region 2-approved PFD, Table 5-2 (Windward and AECOM 2009). The PFD went through multiple rounds of review by Region 2 and was approved on July 31, 2009.  Furthermore, if the CPG correctly understands Region 2's position on peer-reviewed versus non-peer-reviewed literature in other aspects of the LPRSA RI/FS, then the use of values from a thesis is not supported and acceptable. If Region 2 can provide a peer-reviewed paper that supports these results, then the CPG will consider using these results. Otherwise, no change will be made to the revised BERA	Results from the dissertation were published in Aquatic Toxicology 96 (2010) 182–193 – Impaired reproductive health of killifish ( <i>Fundulus heteroclitus</i> ) inhabiting Newark Bay, NJ, a chronically contaminated estuary. This should be reviewed and included in the BERA.

No.	Section	EPA Specific Comment Submitted 5/1/2015	CPG RTC Submitted 9/10/2015 or 9/15/2015	EPA Response to CPG RTC
109	Page 424, Section 7.4.4.3, first paragraph, third sentence	<p>The following statement is made regarding the high HQ for total PCBs in fish eggs calculated for the background when compared to the HQ for the LPRSA:</p> <p><i>“Based on these data, concentrations of total PCBs in small fish appear to be greater in Jamaica Bay/Lower Harbor than in the LPRSA and are indicative of concentrations within an urban environment.”</i></p> <p>The elevated HQ that was calculated is more likely linked to the unknown lipid content or a potential source in Jamaica Bay/Lower Harbor. Plausible scientific rationale needs to be provided instead of generalized statements relating results to urban environments.</p>	Comment can be incorporated into revised document, including discussion of lipid content in fish from Jamaica Bay/Lower Harbor.	Acceptable.
110	Page 433, Section 7.6.3	<p>The text discusses many stressors that may affect the presence of external and internal anomalies in fish, with the exception of contaminants in sediment. It is well documented that PAHs and other contaminants in sediment cause external lesions in benthic fish, especially ictalurids and carp. Elevated concentrations of contaminants in sediment should be viewed as a primary contributor to the presence of external (and possibly internal) lesions in fish. Please revise the text accordingly.</p>	<p>The CPG strongly disagrees with Region 2’s erroneous and inaccurate statement. Chemical impacts and their contribution to risk are the focus of the entire BERA, and for fish, in Section 7. Section 2 presents the ecological setting and includes discussion of other characteristics that may influence the biota at the site. But the majority of the document is dedicated to ascertaining risk from chemical exposure.</p> <p>The data collected as part of the health assessments for the LPRSA fish collected are qualitative in nature only and cannot be used to make conclusive links to chemical concentrations in sediment. Section 7 fairly concludes that “Because of the qualitative nature of the field health observations and the uncertainties associated with their interpretation, conclusive links cannot be established between exposure to chemicals in the LPRSA, effects on LPRSA fish as indicated by field observations, and potential effects on the overall health of fish populations.”</p> <p>No change will be made to the revised BERA.</p>	Revise the fourth sentence in 7.6.3 to read “In addition, the incidence of abnormalities in fish is nearly impossible to attribute to a single factor; rather, it is likely a result of numerous confounding factors, including chemicals, species, age, disease, organic matter, temperature, nutrition, natural parasitic load, season, catch method and geographic location.”
111	Page 434, Section 7.7, second bullet at bottom of page	<p>The text states that “risk estimates based on the dietary LOE were not used to determine COCs for fish”. This raises the question of why this approach was even considered in the evaluation. As outlined in the Problem Formulation section of the draft BERA, the dietary LOE is an approved approach for evaluating this assessment endpoint. Any risk calculated based on diet should not be ignored, and associated chemicals should be retained as potential risk drivers. Please revise the text accordingly. Tissue should be used for all compounds.</p>	<p>Not all LOEs are equally strong. This balancing was taken under consideration when developing risk conclusions. However, the results are clearly presented for each LOE for future risk managers to take into consideration. The revised BERA will present the summarized results per LOE; however the CPG has the obligation to discuss the strengths and weaknesses of each LOE in the overall summary. The presentation of these results will be reviewed and more rationale provided in the revised BERA.</p>	The revised document will be reviewed to confirm that EPA’s comment has been addressed appropriately.
112	Pages 434-441, Section 7.7 and Table 7-35	<p>Several chemicals evaluated using different LOEs indicate risk; however, a majority of these chemicals were dropped as COPECS, based in many cases on the uncertainty in the derivation of values using modeled concentrations. Modeling is an accepted and approved approach in evaluating the fish assessment endpoint. It is acknowledged that uncertainty is inherent in modeling and should be discussed; however, it should not be used to eliminate chemicals as COPECS. Please revise the text and table accordingly.</p>	<p>Not all LOEs are equally strong. This balancing was taken under consideration when developing risk conclusions. While modeling is an acceptable approach for the evaluation of risks, empirical data (actual measured tissue concentrations in fish tissue) are superior to modeled concentrations in egg tissue based on literature assumption for different species and conditions. Thus, when the LOEs conflicted, more confidence was given in the empirical rather than the modeled data.</p> <p>No change will be made to the revised BERA.</p>	Acceptable with respect to not including certain COPECS for which risk was found using modeled data. However, a detailed discussion should be included to highlight the difference in empirical and modeled data.
113	Page 443, Section 8, first bullet	<p>The last statement in this bullet, “use of LPR habitat for breeding used to determine the relative weight for the bird egg measurement endpoint”, is not part of the endpoint that was agreed upon and should be deleted.</p>	<p>The information regarding the availability of breeding habitat is very important and helps put the risk into context. This information will be retained in the revised BERA.</p>	According to the PFD, the assessment endpoint associated with avian species is “Protection and maintenance (i.e., survival, growth, and reproduction) of herbivorous, omnivorous, sediment-probing, and piscivorous bird populations.” Thus, the comment to remove part of the text stands.

No.	Section	EPA Specific Comment Submitted 5/1/2015	CPG RTC Submitted 9/10/2015 or 9/15/2015	EPA Response to CPG RTC
114	Page 445, Section 8.1.2.2, Table 8-3	Please confirm that food ingestion rate for the spotted sandpiper is accurate. Calculations using Nagy 2001 suggest that the value should be 0.034 kg ww/day.	No change to revised BERA.  As noted in footnote "d" to Table 8-3, the spotted sandpiper ingestion rate of 0.033 kg ww/day for common sandpiper reported in Nagy et al. (2001) was adjusted for spotted sandpiper based on the body weight-normalized ingestion rate for common sandpiper (0.64 g ww/g bw/day) and the body weight selected for sandpiper (42.5 g).	Acceptable.
115	Page 448, Section 8.1.2.3, Table 8-4	Risk values using fish of all sizes should be included. For example, great blue herons will eat very large fish and a bounding estimate needs to be presented. In addition, it is unclear why crabs are excluded for the heron.	See response to General Comment No. 3.  In the revised BERA, carp and other large fish (> 30 cm) will also be evaluated as part of the uncertainty assessment as possible prey in the mammalian diet. Carp will not be fed to the avian receptors since it is not an ecologically relevant species (Region 2 directed the CPG to only retain very large carp that are not suitable to be used in an avian dietary model), although the evaluation of medium-sized fish (see Table 2 attached) will be evaluated as part of the uncertainty assessment as possible prey in heron and kingfisher diets. Crabs were excluded from the heron diet given that the literature did not support the consumption of crabs (beyond a very small percentage, if that), as discussed in Section 8.1.2.3 of the BERA.	See EPA response to Comment No. 3. In addition, please note: <ul style="list-style-type: none"> <li>EPA did not direct the CPG to only retain large carp. The data shows that large carp were the fish that were captured and the carp used for the ecological analysis were smaller than those selected for the human health analysis.</li> <li>EPA also never asked that carp be used as a prey item for the kingfisher, only for the great blue heron, which does eat carp in the size range included in the analysis (<a href="https://www.youtube.com/watch?v=1v5w0UK2SvE">https://www.youtube.com/watch?v=1v5w0UK2SvE</a>, link current as of 12/22/2015).</li> <li>Fish of all sizes need to be included in the risk characterization section to present bounding estimates. It is not acceptable to move this discussion to the uncertainty section.</li> <li>A qualitative discussion should be added that discusses the risk for great blue herons that may include blue crabs in their diet.</li> </ul>
116	Page 448, Section 8.1.2.3, Table 8-5	It is unclear why surface water data is limited to that above RM 8.	The CPG notes for Region 2's benefit that surface water included in a drinking water pathway was limited to freshwater only. The BERA defined > RM 8 as freshwater (see Section 8.1.2.3). A footnote can be added to Table 8-5.	Acceptable, based on the drinking water exposure pathway.
117	Page 454-455, Tables 8-7 and 8-8	Tables 8-7 and 8-8, and associated text, should include the same compounds for each diet item so that cumulative exposure can be evaluated. Any COPECs that were identified in sediment, surface water, or tissues should be listed on these tables.	All of the information needed to calculate the doses for each species is presented for the COPECs relevant to those species. Clarification will be provided on why only certain COPECs are presented for certain diet items or areas.	There are nearly twice as many compounds reported for worms as there were for blue crabs in Table 8-7. Please clarify the reason for this finding (e.g., lack of detection, not analyzed, etc.).
118	Page 454, Table 8-7	The percent detected and minimum concentration for mercury in fish ≤ 9 cm (RM > 6) listed in the table are incorrect. It appears that the percent detected cell was shifted. The minimum concentration should be 0.033 mg/kg. Please revise accordingly.	Comment can be incorporated into revised document.	Acceptable.
119a	Page 462, Section 8.1.3.2, fourth paragraph	The endpoint used in the referenced studies is mortality. Therefore, other developmental and reproductive impacts are not addressed. Characterizing the selected TRVs as an overestimate of risk is considered inappropriate, and therefore should be removed, since potentially important sublethal developmental and reproductive impacts are not considered. This comment also applies to Section 8.1.5.	All endpoints are evaluated in the studies and the overall study is evaluated based on the strength of the study and scientific rigor. Endpoints are not simply dropped and the lowest TRV from the literature was selected. Further, the current research indicates differing sensitivities by species. Further explanation will be provided. See attached tables for rationale on each specific TRV.	The revised document will be reviewed to confirm that EPA's comment has been addressed appropriately, consistent with EPA's response to General Comment No. 5.
119b	Page 462, Section 8.1.3.2, fourth paragraph	In addition, the text should refer to ring-necked pheasant, not red-necked pheasant.	Clarification will be made to revise species referenced.	Acceptable.

No.	Section	EPA Specific Comment Submitted 5/1/2015	CPG RTC Submitted 9/10/2015 or 9/15/2015	EPA Response to CPG RTC
120	Page 468, Table 8-14	This is the type of table that should be included in the SLERA and BERA for all receptors/pathways/media.	See response to General Comment No. 2. Please note that all HQ calculations across all receptor groups and LOEs in the BERA are presented in Attachment G.	Including tables similar to Table 8-14 in the body of the text would improve the clarity and transparency of the SLERA and BERA, especially for the major COPECs (i.e., chemicals identified as risk drivers or preliminary COCs), which would greatly aid readers of this document.
121	Page 470, Section 8.2.2, paragraph after Equation 8-5	The text states that prey EPCs were estimated using Equation 8-5 and are represented by whole-body tissue EPCs of each focal species-specific prey species. Equation 8-5 is for deriving bird egg EPCs, which uses the prey EPCs in the calculation. Please revise accordingly.	Comment can be incorporated into revised document.	Acceptable.
122	Pages 470-471, Table 8-15	Footnote “b” is not in the table. Please revise accordingly.	Comment can be incorporated into revised document.	Acceptable.
123	Page 475, Section 8.2.2.2, first paragraph	The biomagnification values used in the calculations were not sufficient. A range of values was provided in the document based on multiple studies. The lowest value, the highest value and a geometric mean of all values should be used to present a range of results.	Rationale was provided for using the selected BMF; the BERA-selected BMFs were based on receptor-specific BMFs, as uptake of COPCs to bird eggs from maternal exposure is expected to vary based on types of bird species, as shown in the wide range of BMFs presented in Table 8-16. The range of acceptable BMFs will be provided in a table.	Acceptable.
124	Page 478, Section 8.2.3.2	The LOAEL that was selected was not based upon one of the selected focal species. However, the text indicates a NOAEL could not be selected because there were no values for the selected focal species. As shown in Table 8-11, there are NOAELs available and the value for Forester's tern, as their diet is similar to a kingfisher, should be selected as a NOAEL for this evaluation.	The BERA HQs are based on LOAELs and if there is an associated NOAEL in the same study, a NOAEL is provided. The suggestion by Region 2 would result in the use of a different species with differing feeding habits. Therefore, CPG requests that Region 2 provide the relevance and how this information would be used in decision making. Otherwise, the original study and endpoint will be used in the revised BERA.	The selected LOAEL is for a ring-turtle dove which is a different species and has a much different feeding habit when compared to a kingfisher. Of the species listed in Figure 8-1, the Forester's Tern has the most similar feeding strategy (i.e., areal fishing for small fish and crustaceans) and should be used.

No.	Section	EPA Specific Comment Submitted 5/1/2015	CPG RTC Submitted 9/10/2015 or 9/15/2015	EPA Response to CPG RTC																																		
125	Page 479, Section 8.2.3.2, first paragraph, third sentence	<p>The text states that chicken toxicity data were eliminated from the data used to select dietary TRVs because of the apparent sensitivity of chickens. Elimination of chicken data is inappropriate. While chickens are commonly viewed to be among the most sensitive avian species tested with regard to dioxin-like effects, they are no more sensitive to such effects than several wild bird species tested. Recent studies have shown several common wild bird species to be as sensitive as or even more sensitive to PCBs and dioxins/furans than the well-studied chicken. Only a small fraction of wild birds have been tested with regard to dioxin/furan exposure, so eliminating a sensitive tested species from a small database may not be protective of non-tested (but potentially sensitive) wild species. Furthermore, designating an avian species as sensitive, highly sensitive, etc. is based only on enzyme induction, and may not fully reveal ecologically significant effects or sensitivity to the numerous documented effects that do not fall within the category of “dioxin-like” effects. Chicken data must be included in the candidate data for selecting avian TRVs. While it is acceptable to have a TRV based on chicken and one for non-chicken, and to present both calculations In Section 8.2.4.2, there should be a discussion regarding the potential impact on HQ derivation if chicken data were included in the selection of TRVs.</p>	<p>The CPG request that Region 2 provide citations for studies showing wild bird species that are as sensitive or more sensitive to PCBs than chicken, as the CPG is unaware of any such studies. Relevant citations are requested.</p> <p>In fact, the data presented in the BERA (Section 8.2.3.2) support that chickens exhibit a greater sensitivity than other wild birds to PCBs and PCDDs/PCDFs: “As discussed in Section 8.1.3.2, avian sensitivity to PCDDs/PCDFs is highly variable and is associated with differences in the structural characteristics of the AH receptor. Chickens are included in the high sensitivity group, whereas the two piscivorous bird receptors, great blue heron and belted kingfisher, are included in the low sensitivity group.”</p> <p>No change will be made to the document pending provision of relevant citations by Region 2.</p>	<p>Relevant agencies and contractor staff evaluated the sensitivity of several bird species to PCB exposures, based on genetic sequences related to AH receptor (i.e., evaluation of dioxin-like effects) for the Kalamazoo River NPL site in western Michigan. This evaluation built upon existing toxicity data and ongoing studies conducted by Sean Kennedy (numerous papers), National Wildlife Research Centre, Environment Canada, Ottawa, ON, Canada.</p> <p>For the Kalamazoo River NPL site, it was determined that 142 bird species have been recorded to occur onsite or have high potential to occur within the NPL site boundaries. Of these, only 7 had been sequenced at the time the Kalamazoo site was first investigated. The attached Word file (Confidence Interval for Number of Sensitive Species.docx) presents a summary of the statistical evaluation of the likelihood that domestic chickens are actually the most sensitive avian species of all those that could occur within the Kalamazoo NPL site.</p> <p>As of 2014, several more species (75) had been sequenced. These additional data (see attached, Avian AHR.xlsx) reveal that bird species as sensitive or nearly as sensitive to PCBs (based on genetic sequencing) as domestic chicken (Group 1, highly sensitive) include red jungle fowl, ruby-throated hummingbird, European starling, and gray catbird – only one of which can be considered closely related to domestic chicken. Approximately half (38) of the remaining bird species were assigned to Group 2 (moderately sensitive), while 32 taxa were assigned to Group 3 (least sensitive).</p> <p>These findings indicate that highly sensitive avian species, again based ONLY on genetic sequencing and NOT on experimentally derived toxicity data, comprise about 7% of birds sequenced. Half (50%) are considered moderately sensitive, and about 40% are considered to have low sensitivity to dioxin-like PCBs.</p> <p>Finally, it is important to note that dioxin-like effects linked to avian genetics and AHR do not address all the other adverse effects not associated with AHR. See Table 3 below, reproduced from DeVito and Henry, 2003.</p> <p><b>Table 3. Toxicity Pathways Documented for Non-Dioxin-Like PCBs</b></p> <table><tr><th rowspan="2">Toxicity Pathway</th><th colspan="4">Organism Class</th></tr><tr><th>Invertebrate</th><th>Fish</th><th>Birds</th><th>Mammals</th></tr><tr><td>Narcosis</td><td>X</td><td>X</td><td>X</td><td>X</td></tr><tr><td>Liver Effects</td><td>N/A</td><td>?</td><td>?</td><td>X</td></tr><tr><td>Neurochemical / behavioral</td><td>?</td><td>?</td><td>?</td><td>X</td></tr><tr><td>Endocrine / Neuroendocrine</td><td>?</td><td></td><td>?</td><td>X</td></tr><tr><td>Immunological</td><td>X</td><td>?</td><td>?</td><td>X</td></tr></table> <p>DeVito and Henry. 2000. NON-DIOXIN-LIKE PCBs: EFFECTS AND CONSIDERATION IN ECOLOGICAL RISK ASSESSMENT. USEPA. Experimental Toxicology Division. National Health and Environmental Effects Research Laboratory. Office of Research and Development</p>	Toxicity Pathway	Organism Class				Invertebrate	Fish	Birds	Mammals	Narcosis	X	X	X	X	Liver Effects	N/A	?	?	X	Neurochemical / behavioral	?	?	?	X	Endocrine / Neuroendocrine	?		?	X	Immunological	X	?	?	X
Toxicity Pathway	Organism Class																																					
	Invertebrate	Fish	Birds	Mammals																																		
Narcosis	X	X	X	X																																		
Liver Effects	N/A	?	?	X																																		
Neurochemical / behavioral	?	?	?	X																																		
Endocrine / Neuroendocrine	?		?	X																																		
Immunological	X	?	?	X																																		
126	Page 484, Section 8.2.4.3	<p>There are several locations in the document where tissue-based comparisons with mummichogs from Jamaica Bay and the LPRSA are made; however, the lipid content from the Jamaica Bay fish is unknown. This should be discussed within the document and information on using an unknown lipid concentration for the comparison should be made (i.e., may over- or under-estimate actual lipid normalized concentration).</p>	<p>Comment can be incorporated into revised document, including discussion of lipid content in fish from Jamaica Bay/Lower Harbor.</p>	<p>Acceptable.</p>																																		
127	Page 485, Section 8.3	<p>The list of COPECs will need to be revised based on comments contained herein, particularly those on the SLERA.</p>	<p>Any changes in COPECs will be reflected in the revised BERA. Please see specific response to SLERA comments.</p>	<p>Acceptable.</p>																																		



No.	Section	EPA Specific Comment Submitted 5/1/2015	CPG RTC Submitted 9/10/2015 or 9/15/2015	EPA Response to CPG RTC
128a	Page 486, Table 8-23	<p>The great blue heron has an egg HQ &gt; 1 for total TEQ, indicating that chemicals contributing to total TEQ should be identified as COCs for avian receptors represented by great blue heron.</p> <p>Use of a species-specific TRV to reduce the HQ is meaningless as the selected TRV should be representative of a particular feeding guild or trophic level represented by great blue heron; protection of this species specifically is not the intent. Reducing the SUF to &lt; 1 for great blue heron is also inappropriate because avian receptors that it represents are likely to forage wherever prey and cover are found.</p> <p>Therefore, Tables 8-23 and 8-24 should identify total TEQ as a COC for great blue heron.</p>	<p>The heron HQ for total TEQ is 1.1 based on the modeled egg approach (using literature-based factors to derive an egg concentration from fish) and using an egg TRV, and the HQ is 10x less (0.17) based on a dietary model (based on empirical fish tissue data from the site and receptor-specific exposure assumptions) and dietary TRV. The low-magnitude HQ of 1.1 based on the egg modeling approach assumes 100% exposure from the LPRSA, despite the heron's large feeding range and use of other nearby habitats, as well as the fact that heron-specific TRVs result in an egg HQ &lt; 1. Based on these multiple lines of information, TEQ was not retained as a COC for heron.</p> <p>No change will be made to the document.</p>	100% exposure is not unreasonable for GBH because GBH will often forage repeatedly in an area that provides food and cover, especially in an urban area that has limited habitat in other areas. All exposure scenarios with HQs equal to or exceeding 1 should be identified as associated with unacceptable risk. A finding that other scenarios result in lower HQs does not negate the results of scenarios with unacceptable risk.
128b	Page 486, Table 8-23	Additionally, the prey items for the great blue heron and belted kingfisher are larger, and contain higher concentrations of contaminants, than the prey items for the spotted sandpiper. Given this, it is likely that their exposure and therefore their risk is greater. This should be discussed in the text. For transparency issues, all of the avian receptors that were evaluated should be included in Table 8-23.	<p>There are multiple factors that go into the determination of risk, including concentration in the prey, exposure parameters (including body size of the receptor), and the toxicity factors used.</p> <p>See response to General Comment No. 3. In the revised BERA, the evaluation of medium-sized fish (see Table 2, attached) will be evaluated as part of the uncertainty assessment as possible prey in heron and kingfisher diets. A table of all bird receptors and their respective HQs and LOEs will be developed.</p>	Acceptable.
128c	Page 486, Table 8-23	For transparency issues, all of the avian receptors that were evaluated should be included in Table 8-23.	A table of all bird receptors and their respective HQs and LOEs will be developed.	Acceptable.
129	Page 493, Section 9.1.2.3	Section 9.1.2.3 of the document should be modified to address the comments on Table 9-4.	Comment can be incorporated into revised document, as appropriate.	Acceptable.
130	Page 494, Table 9-4	The labels for the evaluation completed for the mink based on prey composition need to be clarified. There are two scenarios that should be evaluated: (1) Mink – aquatic prey only with blue crab at 33.5% and fish at 66.5%, and (2) Mink – aquatic and terrestrial prey with blue crab at 16.5%, fish at 34%, and terrestrial prey at 49.5%, with the terrestrial portion being set to zero as there is no terrestrial prey contaminant data. A third scenario, termed Mink – aquatic prey with estimated terrestrial prey using blue crab at 16.5%, fish at 34%, and terrestrial prey at 49.5%, with the terrestrial concentration being equivalent to the fish concentration, may be included if desired.	The CPG requests that Region 2 provide peer-reviewed citations for the requested scenarios; and then multiple prey scenarios will be evaluated according to comment.	Citations are not needed as clarification and bounding is all that is being requested. EPA wants to see risk from an all aquatic diet and a diet that is half aquatic and half terrestrial, with the terrestrial set to zero. The half aquatic and half terrestrial diet, with terrestrial equal to zero, should be added, although the risk should be the same as the all aquatic diet.
131	Page 494, Section 9.1.2.3	All fish sizes should be included in the mink diet composition as the mink is able to catch all sizes of fish and it is able to prey/scavenge fish that wash up on the shore. It is acceptable to have multiple calculations showing the potential risk for all fish, a subset based on sizes, and a distribution of risk by size.	See response to General Comment No. 3. Carp will be added as a portion of mink and river otter diet as part of the uncertainty evaluation, although the literature supports that these larger fish (> 30 but < 70 cm in length) would be a small fraction of their diet.	Partially acceptable. Carp must also be added to the risk characterization section. See EPA response to General Comment No. 3.
132	Page 497, Section 9.1.2.4	White sucker, carp, channel catfish and brown bullhead should all be included.	Note that the catfish group includes white sucker, channel catfish, and brown bullhead (see footnote “d” of Table 9-6). See response to General Comment No. 3. In the revised BERA, carp and other large fish will also be evaluated as part of the uncertainty assessment as possible prey in the mammalian diet.	EPA does not agree that carp are not considered dietary items for mink, and that such exposures should be considered only in the uncertainty assessment. Carp are often found in shallow water, are slow, and are often left on shore by fishermen; thus, they are commonly available to predators and scavengers. As indicated in other responses, carp are alternate species and must be included in the risk characterization section.
133	Pages 498-499, Table 9-7	Please make the following revisions: a. The mean concentration for selenium in bass ≤ 30 cm (site wide) should be 0.62 mg/kg. b. The total number of samples for white perch ≤ 30 cm (site wide) should be 22. It appears that the sample LPR1- MAWB-Ind145 was excluded from the calculation.	<p>The mean of the three bass samples &lt; 30 cm is reported correctly as 0.56 mg/kg. The total number of white perch ≤ 30 cm is correctly reported as 21 (the specimen length for sample LPR1-MAWB-Ind145 is 32.1 cm).</p> <p>No change will be made to the document.</p>	The revised document will be reviewed to confirm that EPA's comment has been addressed appropriately. Please include fish specimen size data in the revised BERA. This will allow the reader to evaluate the data presented in the tables and text using the BERA as a standalone document.

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134	Page 509, Table 9-13	The footnote to Table 9-13 indicates an FIR of 0.16 was used for mink TRV extrapolation (from dietary TRV, Chapman 2003). Table 9-3 shows an FIR of 0.14 was used for mink. It appears that 0.16 is the upper limit of the range indicated in footnote "d" in Table 9-3. Please add clarification to the text and tables.	Comment can be incorporated into revised document to reconcile this discrepancy.	Acceptable.
135	Page 512, Section 9.1.4.2, bullets	In the 5th bullet, please provide the rationale for the assumption that only 50.5% of the mink diet comes from the LPRSA. In the 6th bullet, consider evaluating differences in fish size. In the 8th bullet, please clarify what crab data were used, and check for consistency throughout the document.	Rationale is provided in Section 9.1.2.3. Document will be revised to clarify and provide justification.	Acceptable.
136	Page 522, Section 9.1.4.2	Future use and restoration activities should be considered in the text.	The CPG disagrees. The BERA provides an evaluation of current conditions and the planned future use and restoration activities are beyond the scope of this document.  No changes required.	EPA disagrees with the CPG response. The original comment must be addressed in the next draft of the BERA.
137	Page 523, Section 9.1.4.3, first paragraph	Please provide additional rationale for using fish values as a surrogate for blue crab. The last sentence is not sufficient. Explanation is needed regarding whether this approach is supported by the LPRSA data (i.e., are concentrations from fish less than 30 cm similar to blue crab concentrations?).	Comment can be incorporated into revised document.	Acceptable.
138	Pages 523-524, Table 9-18	As was discussed in a previous comment, lipid content from the Jamaica Bay fish samples is unknown. This should be discussed within the document and information on using an unknown lipid concentration for the comparison should be made (i.e., may over- or under-estimate actual lipid normalized concentration).	Comment can be incorporated into revised document, including discussion of lipid content in fish from Jamaica Bay/Lower Harbor.	Acceptable.
139	Page 525, Section 9.1.6	The summary will need to be revised, based on the comments received.	Comment can be incorporated into revised document.	Acceptable.
140	Page 530, Section 11	Recommend that the conclusion state that due to a lack of TRVs for herptiles, the potential risk and impact to herptile populations is unknown.	Comment can be incorporated into revised document.	Acceptable.
141	Page 532, Section 13	This entire section will need to be revised to reflect the changes made to the rest of the document.	Comment can be incorporated into revised document.	Acceptable.
142	Pages 533-535, Table 13-1	This table should present all unacceptable risks (HQ > 1) regardless of LOE or weighting of various LOE. As currently presented, there is too much interpretation in the conclusions reached, and the ecological significance of potentially important risk estimates is minimized (i.e., "low likelihood of impact") due to various choices or assumptions made in the draft BERA. These include selection of TRVs, elimination of receptor species from full evaluation, application of uncertainties, designation of some LOE as weak, low weighting applied to LOE, use of unsupported categories of risk (e.g., low, moderate, or high likelihood of risk), and the effect of non-chemical stressors on ecological receptors. This comment also applies to any similar text in Section 13 of the draft BERA.	CPG disagrees that risk estimates are minimized. The document gives a range of risk estimates and uses the best scientific data and literature to develop a realistic and protective risk estimate. Because there are multiple LOEs in a BERA, and not all LOEs are equal, it requires professional judgment to determine the ultimate potential for risk.	EPA disagrees with the CPG response. The original comment must be addressed in the next draft of the BERA.
143	Appendix A - SLERA, General	Several chemicals are eliminated as COPECs in various media (sediment, surface water, and tissue) due to a lack of screening levels and TRVs. This approach is inappropriate and these chemicals should be retained for further evaluation in the BERA.	It should be noted that COIs with no TRVs were discussed in the SLERA for each LOE evaluated. As discussed with Region 2 in the May and June 2015 Region 2-CPG conference calls, this discussion can be moved to/repeated in the appropriate uncertainty discussion sections of the revised BERA.	The revised document will be reviewed to confirm that EPA's comment has been addressed appropriately, consistent with EPA's response to General Comment No. 5.

No.	Section	EPA Specific Comment Submitted 5/1/2015	CPG RTC Submitted 9/10/2015 or 9/15/2015	EPA Response to CPG RTC
144	Appendix A - SLERA, General	The SLERA should not reference the BERA at all, except at the end to say that a BERA is needed.	As discussed with Region 2 in the May and June 2015 Region 2-CPG teleconference calls, the SLERA will not reference the BERA; the SLERA will be a standalone document even though it is part of the BERA.	Acceptable.
145	Appendix A - SLERA, General	While reviewing the document, it is not clear which values were used for screening. This needs to be modified.	As stated explicitly in Section 3.3: “Receptor pathway-specific screening-level effects thresholds or TRVs used in the SLERA are presented in Attachment A3.”	As stated explicitly in many comments, the transparency of the document and ease of locating information is not adequate. The original comment must be addressed in the next draft of the BERA.
146 <sup>1</sup>	Appendix A - SLERA, General	Chemicals should not be screened out based on species. The maximum detected concentrations should be used for each compound during the SLERA screening. Specific species can be examined in the BERA, as appropriate.	<p>This comment directs CPG to take an approach inconsistent with previous agreements and documentation. Per Appendix A of the RARC Plan (Windward and AECOM 2013), which underwent multiple reviews and comments by Region 2, “Screening-level values are medium and receptor group specific. The result is a set of COPEC-receptor pairs to be evaluated in the BERA.” Region 2 did not comment on this in its multiple reviews of the RARC Plan and Appendices. The last round of Region 2 comments on the RARC Plan and Appendices (January 31, 2014) only had three comments regarding Appendix A: an editorial change, the removal of the word “urban,” and the clarification that TRVs would be submitted with the BERA.</p> <p>It is also unclear how Region 2 would propose the screening for dietary COPECs (e.g., for fish, birds, and mammals) if receptor-specific screens are not conducted.</p> <p>As discussed with Region 2 in the May and June 2015 Region 2-CPG teleconference calls, the SLERA will screen by species, but if any chemicals come through for any species in a given media, those chemicals will be evaluated for focal species for that media in the BERA.</p>	The CPG appears to misunderstand the intent of this comment. Individual species should not be evaluated in the SLERA. The maximum detected concentration for each compound in all species should be used for screening purposes.
147	Appendix A - SLERA, General	<p>Carp must be included in the SLERA. The arguments presented for not including carp in the draft SLERA (and the draft BERA) are unacceptable. It is irrelevant whether carp are introduced or native, are considered a stressor, or are considered too large for upper trophic level receptors to consume. In many locations, carp are often caught by humans and either consumed or disposed of on the bank, where they are available to receptors such as raccoons, mink, and avian carnivores. Furthermore, carp likely represent the most highly exposed fish taxon, and eliminating carp from the analysis results in a loss of important exposure data.</p> <p>The SLERA and BERA should be revised to incorporate carp in the analysis.</p>	<p>See response to Comment No. 3. Carp were not included as representative fish in the Region 2-approved PFD.</p> <p>In the revised BERA, carp and other large fish will be evaluated as part of the uncertainty assessment as possible prey in the mammalian diet. Carp will not be fed to the avian receptors since it is not ecologically relevant, although the evaluation of medium-sized fish (see Table 2 attached) will be evaluated as part of the uncertainty assessment as possible prey in heron and kingfisher diets.</p>	See EPA response to General Comment No. 3. Carp and other large fish must be evaluated in the risk characterization section, as prey for great blue heron, river otter and mink.

<sup>1</sup> Comments 102 and 180 also relate to this issue. Per the RARC Plan, “Screening-level values are medium and receptor group specific. The result is a set of COPEC-receptor pairs to be evaluated in the BERA.” EPA did not comment on this in their multiple reviews of the RARC Plan and Appendices (Windward and AECOM 2013).

No.	Section	EPA Specific Comment Submitted 5/1/2015	CPG RTC Submitted 9/10/2015 or 9/15/2015	EPA Response to CPG RTC
148	Appendix A - SLERA, General	Significant modification is needed to the SLERA, and these modifications must be carried through to the BERA. Substantial revisions are needed to provide the most conservative exposure and toxicity parameters, as required by ERAGS, to ensure that the SLERA provides defensible conclusions and that potential ecological threats are not overlooked. Conservative effects thresholds must be used in the assessment (i.e., NOAELs). Estimates of exposure must be generated using comprehensive data on the site and conservative assumptions regarding exposure (e.g., area use factor of 100%, bioavailability of 100%, most sensitive life stage, minimum body weight to maximum ingestion rate, 100% of diet consists of the most contaminated dietary component, highest bioaccumulation factor reported in the literature, etc.).	<p>As Region 2 is aware, the CPG delivered the TRV document (Appendix A, Attachment B3) in August 2011, well ahead of submitting the SLERA (and BERA). Region 2 has had ample time to provide comments on proposed TRVs in the interim; however, Region 2 made the decision to not provide any comments on the TRVs in the 2011 document until May 2015.</p> <p>Region 2-recommended TRVs, as documented in the 2007 and 2014 FFSs, were evaluated by CPG. Attachment A3-1 presents a detailed evaluation of all 2007 FFS TRVs, the majority of which were not found to be technically valid for use in a risk assessment. Appendix D.1 of CPG's comments on the 2014 FFS also presented a detailed evaluation of all 2014 FFS TRVs, again finding the majority of studies invalid for use in a risk assessment. This critique of Region 2's TRVs (which are the assumed TRVs Region 2 is recommending that CPG use for the SLERA) is compiled in the attached TRV tables (a few additional TRVs are recommended specifically in these comments and are addressed in the attached tables). Only the few TRVs provided by Region 2 that are found to be technically valid will be used in the SLERA.</p> <p>Exposure parameters that were used in the BERA are considered appropriately conservative and scientifically based. If Region 2 has any specific comments (other than those noted in these comments) on an exposure parameter; then Region 2 needs to advise the CPG prior to revising the BERA.</p> <p>It is unacceptable on the part of Region 2 and its Partner Agencies to withhold or decline to provide information pertinent to revising the BERA until after the delivery of the revised BERA.</p>	As has been discussed, the most conservative TRVs must be used in the SLERA. The CPG must also include the TRVs used in the FFS and those recommended in EPA's comments on the BERA, and the CPG may also include what they feel are more appropriate values, which would be presented alongside the other values to bound the results.
149	Appendix A - SLERA, General	Hazard quotients need to be calculated for each contaminant and HIs need to be calculated for groups of contaminants with the same or similar mode of toxicity.	Region 2 is requested to provide the proposed use of calculating HIs in the SLERA when the purpose of the SLERA is to identify COPECs for evaluation in the BERA. No criteria have been provided by which to evaluate HIs for groups of chemicals; rather, screening thresholds exist only to screen singular chemicals. Exceptions, of course, include sums of PAHs, PCBs, etc., which are screened as sums.	Acceptable. EPA was referring to the sum of PAHs, PCBs, etc.
150	Appendix A - SLERA, General	"Uncertain" COPECs must be included in the list of COPECs that will be evaluated in the BERA.	The CPG notes for the Region 2's benefit that COIs with no TRVs were discussed in the document for each LOE evaluated. This discussion will be moved to/repeated in the appropriate uncertainty discussion sections of the revised BERA.	Acceptable.
151a	Appendix A - SLERA, General	The objectives identified in the SLERA are not consistent with EPA guidance (EPA, 1997; EPA, 1998) and must be revised; they included identification of substances that can be eliminated from further consideration because they are unlikely to pose risks to ecological receptors, identification of contaminants of potential ecological concern (COPECs) that warrant further consideration in the BERA, and identification of chemicals that will be addressed in the BERA uncertainty section.	<p>The CPG disagrees with Region 2's comment; the objectives are consistent with EPA guidance.</p> <p>Note that EPA (1998) states, "the results of the screening-level risk assessment (Steps 1 and 2) should have indicated which contaminants found at the site can be eliminated from further consideration and which should be evaluated further..."</p>	This appears to be a semantic issue. EPA wants the specific language from the EPA guidance document to be included. Although the CPG text may be similar, EPA requires the actual language from the guidance to be used.
151b	Appendix A - SLERA, General	A SLERA should not identify COPECs that will be addressed in the uncertainty section of a BERA. Conservative toxicity screening values (TSVs) are used in a SLERA to identify contaminants and exposure pathways that might pose ecological threats. If no TSVs are available for a substance, then that substance is carried into the BERA. In the BERA, less conservative toxicity reference values (TRVs) are typically used to identify the substances that are causing or substantially contributing to ecological risks. If TRVs are not available or cannot be developed for certain COPECs in the BERA, they are identified as uncertain COPECs in the BERA (not during the SLERA).	The CPG notes for Region 2's benefit that COIs with no TRVs were discussed in the SLERA for each LOE evaluated. This discussion will be moved to/repeated in the appropriate uncertainty discussion sections of the revised BERA.	Acceptable.

No.	Section	EPA Specific Comment Submitted 5/1/2015	CPG RTC Submitted 9/10/2015 or 9/15/2015	EPA Response to CPG RTC
152	Appendix A - SLERA, General	To provide some context, the SLERA should include a summary of the problem formulation and diagrams that illustrate the conceptual site model.	Comment can be incorporated into revised document. A CSM and summary of the problem formulation will be added.	Acceptable.
153	Appendix A - SLERA, General	The SLERA should present the assessment and measurement endpoints that are relevant to the SLERA, not those that are developed for the BERA. Table 1-1, Summary of BERA Assessment and Measurement Endpoints and Data Used for the SLERA, should be revised so that it describes SLERA assessment and measurement endpoints rather than BERA endpoints. The SLERA should use conservative screening values (e.g., use of bivalve-specific screening values is inappropriate in Table 1-1, Assessment Endpoint 4).	<p>The CPG disagrees with this comment, which directs CPG to take an approach inconsistent with previous agreements and documentation, specifically the Region 2-approved PFD Table 5-2 (July 31, 2009) (Windward and AECOM 2009). Assessment endpoints in the SLERA and BERA are consistent with those presented in the Region 2-approved PFD (Windward and AECOM 2009).</p> <p>It is unclear what assessment and measurement endpoints specific to the SLERA only Region 2 is now proposing.</p>	<p>This comment and Comment 153 were discussed during a 5/14/2015 conference call between EPA and the CPG, and the CPG indicated verbally during the call it had re-read the SLERA and understood EPA's concerns. On 5/21/2015, EPA sent the following response to the CPG via email:</p> <p style="padding-left: 40px;">In general, the PFD lists assessment endpoints for the BERA, not the SLERA. The endpoints for the SLERA should be more generic, similar to the receptors presented in the Conceptual Site Model. To address these comments specifically, please remove Table 1-1, combine Tables 1-2 and 1-3, and remove references to the BERA in this new combined table.</p> <p>The CPG must make the changes indicated above.</p>
154	Appendix A - SLERA, General	Where concentrations in tissue will be compared to a critical tissue residue (CTR; e.g., in Table 1-1), that value should be provided.	The CPG notes for Region 2's benefit that screening-level values are all presented in Attachment 3 (TRV deliverable) of Appendix A (SLERA). In addition, all the calculations (e.g., the screening-level TRVs compared to the maximum exposure critical tissue residues) are presented in Attachment A2. Note that there are 14 tables showing the screening comparisons, and some tables have more than 900 cells populated in the table (e.g., fish tissue); it is not practical to include so much data as a table in the main text. As noted in Section 3.4, "Calculated HQs for all LOEs evaluated are presented in Attachment A2."	The transparency of the document and ease of locating information is not adequate. The CPG must make the changes as directed by EPA to make the document more clear and transparent.
155	Appendix A - SLERA, General	Ecological receptor groups and focal species should not be identified in the SLERA (i.e., Table 1-2, Summary of Ecological Receptors and Focal Species for the LPRSA BERA, should be eliminated from the SLERA) since the TSVs used are generic and broadly applicable to aquatic organisms and aquatic-dependent wildlife.	<p>The CPG disagrees with Region 2's comment, which directs CPG to take an approach inconsistent with previous agreements and documentation. Receptors in the SLERA and BERA are consistent with those presented in the Region 2-approved PFD (Windward and AECOM 2009). See PFD Table 5-1 (Windward and AECOM 2009). The PFD went through multiple rounds of review by Region 2 and was approved on July 31, 2009.</p> <p>Per Appendix A of the RARC Plan (Windward and AECOM 2013), "Screening-level values are medium and receptor group specific. The result is a set of COPEC-receptor pairs to be evaluated in the BERA." Region 2 did not comment on this in its multiple reviews of the RARC Plan and Appendices.</p>	<p>This comment and Comment 151 were discussed during a 5/14/2015 conference call between EPA and the CPG, and the CPG indicated verbally during the call it had re-read the SLERA and understood EPA's concerns. On 5/21/2015, EPA sent the following response to the CPG via email:</p> <p style="padding-left: 40px;">In general, the PFD lists assessment endpoints for the BERA, not the SLERA. The endpoints for the SLERA should be more generic, similar to the receptors presented in the Conceptual Site Model. To address these comments specifically, please remove Table 1-1, combine Tables 1-2 and 1-3, and remove references to the BERA in this new combined table.</p> <p>The CPG must make the changes indicated above.</p>
156a	Appendix A - SLERA, General	According to EPA guidance (EPA, 1997; EPA, 1998), chronic no observed adverse effect levels (NOAELs) should be used as a screening ecotoxicity value when they are available. When chronic NOAELs are not available but a chronic lowest observed adverse effect level (LOAEL) is available, the screening ecotoxicity value should be estimated by multiplying the chronic LOAEL by 0.1. It appears that this guidance was not followed for all COPECs and all media types. The following concerns are noted based on a cursory evaluation of the selected TRVs (additional exceptions are likely to be identified based on a more in-depth analysis):	NOAELs were used when available from the same study as the LOAEL, per acceptability criteria to bound the toxicity value. Extrapolation factors are arbitrary and the CPG requests Region 2 provide literature citations for use of extrapolation values.	The citation was previously provided in EPA 1997. See comment 214.

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156b	Appendix A - SLERA, General	<p><u>Surface Water TRVs</u>– The EPA criterion continuous concentration (CCC) for chromium-VI should be selected for total chromium because total chromium could be primarily in the Cr-VI form; the EPA CCC for lead should be used for lead in the freshwater and marine areas; the EPA CCC of 8.2 µg/L should be used for nickel in the marine areas; the EPA CCC of</p> <p>5.0 µg/L should be used for selenium in the freshwater areas; alternative TRVs should be selected for silver; the EPA criterion maximum concentrations (CMCs) that were selected represent acute toxicity thresholds; the EPA CCC of 0.072 µg/L should be used for TBT in the freshwater areas.</p>	Region 2's TRVs will be evaluated, and if they meet the acceptability criteria, will be used in the SLERA.	Not acceptable. All EPA Region 2 TRVs must be included in the SLERA as directed by EPA.
156c	Appendix A - SLERA, General	<p><u>Sediment TRVs</u>– NJDEP freshwater and marine “high” and “low” screening level (SL) values are presented in Attachment A2; the source of these SLs should be identified in the table; unless the NJDEP “high” SL values represent NOAELs, they should be removed from the SLERA; there are numerous candidate sources of TRVs for freshwater and marine sediments. The SLERA should compile candidate TRVs for each COPEC and provide a rationale for selecting one for use in the SLERA; the source of the marine SL values for plants is not identified in Attachment A2 so it is not possible to evaluate the appropriateness of these SL values.</p>	<p>The sources of all the sediment TRVs used for screening benthic invertebrates are presented in Table 4-1 of Attachment 3-1 of the SLERA. The sources of all the water TRVs used for aquatic plants are presented in Table 10-2 of Attachment 3-1 of the SLERA.</p> <p>No change will be made. The direction to use sediment values other than NJDEP values is contrary to Region 2's prior direction given as comments to the RARC Plan. The sediment screening thresholds used in the SLERA for benthic invertebrates are based on the values provided by Region 2 in its comments (received July 11, 2011) on the draft RARC Plan (February 10, 2011). These sediment values were based on NJDEP SLs and, in some cases, on FFS PRGs.</p>	The information in the PFD and RARC Plan and Appendices address presentation of endpoints and data for the BERA, not the SLERA. The CPG must present assessment and measurement endpoints appropriate to the SLERA.
156d	Appendix A - SLERA, General	<p><u>Sediment TRVs</u>–However, a plant-specific screen should not be included in the SLERA; risks to plants associated with exposure to contaminants should be assessed in the BERA.</p>	As discussed with Region 2 and documented in the June 19, 2015, letter, plant-specific values will be used in the SLERA.	As was stated via email on 5/21/2015 and again in EPA's 6/19/2015 letter to the CPG, the point of this comment was that in the SLERA, the most conservative value for sediment should be used, regardless of the receptor for which it is related. As long as the most conservative value is used for both plants and other receptor groups for sediment, it is okay to have multiple sediment screening in the SLERA.
156e	Appendix A - SLERA, General	<p><u>Tissue TRVs</u>– NOAELs for invertebrates, fish, birds, and mammals have not been estimated for many of the substances included in the screening table for invertebrates, fish, birds, and mammals; the screens for invertebrates, fish, birds, and mammals are therefore incomplete.</p>	NOAELs were used when available from the same study as the LOAEL. These are no-effect concentrations and therefore meaningless from a risk decision perspective. CPG requests Region 2 to provide citations of how decisions will be made using no-effect concentrations.	As per EPA ERAGs, page 2-4, “screening ecotoxicity values should be equivalent to a documented and/or best conservatively estimated chronic NOAEL.” The decision point is whether specific compounds are carried through to the BERA. This concept is a central component of conducting a SLERA.
157	Appendix A - SLERA, General	The “Notes” for several tables (e.g., 4-9, 4-10, 4-12, 4-13, and 6-2) state that the majority of the total mercury in fish and invertebrate tissue is in the form of methylmercury. It is important to clarify that for lower trophic level fish and invertebrates, methylmercury is typically only slightly above 50% of the total mercury.	Comment can be incorporated into revised document.	Acceptable.
158	Appendix A - SLERA, General	The screening tables for water and tissues were not examined in detail. However, based on the review of the screening tables for sediments, it is likely that the screening for these media will need to be revised to correct errors and omissions.	The CPG requests Region 2 provide the “errors and omissions.”	Once the TRVs are revised appropriately, the screening issue will resolve itself.
159	Appendix A - SLERA, General	Hazard indices (HIs) need to be calculated for all groups of contaminants with the same or similar modes of toxicity (e.g., HIs were not calculated for divalent metals, PAHs, etc.).	See response to specific Comment No. 149.	Acceptable, please see EPA response to Comment No. 149.

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160	Appendix A - SLERA, Page 4, Table 1-1, Assessment Endpoint 4, first Measurement Endpoint	Text should be added to state that chemical concentrations in tissue from in situ caged bivalves will be compared with literature-based CTRs.	Note that per the Region 2-approved bivalve QAPP in WS #9, no quantitative evaluation of <i>in situ</i> caged mussels is required. However, for completeness, these tissue concentrations were compared to thresholds for another LOE. This information is provided in the SLERA (Section 2.1.3; results of this comparison are presented in Table 4-10; selenium was the only COPEC identified for mussels). The information will be provided in the revised BERA and qualitatively discussed.	Acceptable.
161a	Appendix A - SLERA, Page 7, Table 1-1	Endnote 'b' states that a dietary model will be used for contaminants that may be metabolized or regulated by the fish. If tissue concentrations were measured in the fish, then these concentrations should be compared to the appropriate TRV. Dietary models should be used for all COIs, not just those considered "regulated/metabolized."	See response to specific Comment No. 97.	See responses to Comments 97 and 99. Measured concentrations of all potentially hazardous chemicals in fish tissue should be compared to fish tissue (residue-based) TRVs. At the SLERA stage, residue-based TRVs should include no effects values, where available.
161b	Appendix A - SLERA, Page 7, Table 1-1	Endnote 'g' states that surface sediment data were not used in the screen for amphibians and reptiles because TRVs were not available. The exposure to contaminants in the sediment still needs to be evaluated as per Figure 1-1 (p. 12).	No change. It is unclear how this endpoint is to be evaluated given the lack of relevant TRVs.	The evaluation would be qualitative in nature with the conclusion that there are limited TRVs and the potential risk to amphibians and reptiles is unknown. The original comment must be addressed as directed by EPA.
162	Appendix A - SLERA, Page 9, Table 1-3	<p>Sediment chemistry should be added as a 'type of data' for fish, birds, mammals and herbivores, as they will be subject to inadvertent sediment ingestion. In fact, text (p. 16) and Table 3-1 (p. 30) states that the incidental sediment ingestion dietary component will be used in dose calculations for fish, macroinvertebrates, birds, and mammals. More specifically, Table 1-3, Ecological Receptor Groups and Types of Data Used for COPEC Identification in the SLERA, is incomplete and should also include the following:</p> <p>Sediment chemistry data should be used to assess potential risks to benthic fish.</p> <p>Fish egg tissue chemistry data should be used to assess potential risks to fish (e.g., for PCDDs/PCDFs, PCBs, selenium, etc.),</p> <p>Sediment chemistry data should be used to assess potential risks to sediment-probing birds,</p> <p>Sediment chemistry data and dietary dose should be used to assess potential risks to amphibians, and</p> <p>Dietary dose should be used to assess potential risks to reptiles.</p>	<p>This comment directs CPG to take an approach inconsistent with previous agreements and documentation and is, in part, inconsistent with Region 2's own FFS ERA (Louis Berger et al. 2014). See Sections 4.2.2-4.2.4 and 4.3.1 of the SLERA, and PFD Table 5-2 (Windward and AECOM 2009). The PFD went through multiple rounds of review by Region 2 and was approved on July 31, 2009.</p> <p>In addition, Appendix A of the RARC Plan (Windward and AECOM 2013) states, "Sediment COPECs will be identified for benthic invertebrates and aquatic plants only. Sediment COPECs will not be identified for amphibians or reptiles, inasmuch as there are relatively few data available to develop toxicity screening values for amphibians and reptiles exposed to chemicals in either sediment or soil. Screening for COPECs for amphibians and reptiles will be conducted using only surface water data (Section 2.2). Sediment COPECs will not be identified for fish because the evaluation of uptake from sediment to fish is incorporated as part of the tissue evaluation (Section 2.3) and dietary assessment. COPECs for surface sediment will be identified according to the process outlined in Figure 2-1."</p> <p>Region 2's comment regarding reptiles is inconsistent with the FFS ERA (Louis Berger et al. 2014) (see Section 4.1.3, pages 4-15 to 4-16).</p> <p>The CPG also disagrees with Region 2's contention that the SLERA is incomplete. The SLERA does evaluate the following endpoints in Region 2's comment list: fish egg (b) and sediment chemistry to birds (as part of diet) (c).</p> <p>Sediment exposure for fish is evaluated using the tissue residue and dietary LOEs (a). The evaluation of direct sediment exposure for fish was not listed as a measurement endpoint under Assessment Endpoint 5 in the Region 2-approved PFD (Windward and AECOM 2009).</p> <p>The evaluation of sediment data and dietary doses for amphibians and reptiles is not feasible given the lack of toxicity data (d, e). The evaluation of dietary doses for amphibians and reptiles is inconsistent with the assessment endpoints presented in the Region 2-approved PFD (Windward and AECOM 2009); this measurement endpoint was not listed as under Assessment Endpoint 9 in the Region 2-approved PFD.</p>	<p>There is no inconsistency in EPA's comments. EPA is referring to the SLERA, which needs to address in a conservative manner all potential exposure pathways, as compared to a BERA.</p> <p>As was stated in a 5/21/2015 email from EPA to the CPG and again in EPA's 6/19/2015 letter to the CPG, an "x" is required in the sediment chemistry column for benthic omnivorous fish, invertivorous fish, piscivorous fish, sediment-probing invertivorous birds, piscivorous mammals and amphibians/reptiles. This is consistent with Figures 5-1 through 5-3 of the PFD.</p>

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163a	Appendix A - SLERA, Page 12, Figure 1-1	Figure 1-1, Decision Points Considered in the SLERA, should be revised to be consistent with EPA guidance (EPA, 1997; EPA, 1998).	The CPG disagrees with Region 2's comment that decision points in the SLERA are inconsistent with EPA guidance. The SLERA process outlined in Appendix A of the BERA is consistent with the process outlined in Figure 1-1 of Appendix A of the RARC Plan (Windward and AECOM 2013). Appendix A of the RARC Plan underwent multiple reviews and comments by Region 2. The last round of Region 2 comments on the RARC Plan and Appendices (January 31, 2014) only had three comments regarding Appendix A: an editorial change, the removal of the word "urban," and the clarification that TRVs would be submitted with the BERA.	The RARC plan provides information to be used in the BERA. This comment is focused specifically on the SLERA. As EPA and the CPG discussed on 5/14/2015, the SLERA is a stand-alone document and conservative in nature. The changes directed by EPA in this comment must be made.
163b	Appendix A - SLERA, Page 12, Figure 1-1	The SLERA should include a selection of conservative TSVs (chronic no observed effect levels), development of exposure estimates (EPCs), and calculation of hazard quotients.	See response to specific Comment No. 148.	See response to Comment No. 148.
163c	Appendix A - SLERA, Page 12, Figure 1-1	It is not appropriate to eliminate any receptor-exposure pathway pair based on lack of empirical data, lack of a TRV, or lack of alternative methods for evaluating risks.	The CPG notes for Region 2's benefit that COIs with no TRVs were discussed in the SLERA for each LOE evaluated. This discussion will be moved to/repeated in the appropriate uncertainty discussion sections of the BERA.	The revised document will be reviewed to confirm that EPA's comment has been addressed appropriately.
163d	Appendix A - SLERA, Page 12, Figure 1-1	In addition, receptor-exposure pathway pairs cannot be eliminated in the SLERA based on generic rationale regarding limited potential for bioaccumulation; all such receptor-exposure pathway pairs must be carried forward into the BERA and evaluated.	Per Appendix A of the RARC Plan, "Screening-level values are medium and receptor group specific. The result is a set of COPEC-receptor pairs to be evaluated in the BERA." Region 2 did not comment on this in its multiple reviews of the RARC Plan and Appendices.  As discussed with Region 2 in the May and June 2015 Region 2-CPG teleconference calls, the SLERA will screen by species, but if any chemicals come through for any species in a given media, those chemicals will be evaluated for all species for that media in the BERA.	Acceptable.
164	Appendix A - SLERA, Page 15, Section 2.1	The sediment chemistry data used in the SLERA that are identified in Section 2.1, Data Availability and Selection, are different from those presented in Table 1-1 (the 2008 coring data are not identified in Table 1-1).	Comment can be incorporated into revised document. These sections will be reviewed for consistency.	Acceptable.
165	Appendix A - SLERA, Page 16, Section 2.1	Text states that surface sediment data collected from all dredge locations (RM 10.9 and Lister Ave dredge area) were excluded. This statement appears to conflict with other text (e.g., pp. 15 and 26), which specifically includes RM 10.9 data. Please revise for consistency.	Comment can be incorporated into revised document. These sections will be reviewed for consistency.	Acceptable.
166	Appendix A - SLERA, Page 16, Section 2.1.1	The definition of "mudflat areas" used in Section 2.1 (and Section 3.2.2.1, Body Weight and Ingestion Rates) is inappropriate; any unvegetated intertidal areas that are comprised of fine grain sediment (mud) should be considered "mudflat areas" for the purposes of the risk assessment. Intertidal areas including larger grain size sediment should be evaluated separately.  Table 2-1 should be modified to reflect this comment.	The CPG disagrees with this comment, which is based on a false premise and also inconsistent with Region 2's 2014 FFS/RI and previous agreements.  This definition is consistent with presentations given to Region 2 on March 6, 2014, and Region 2-approved QAPPs. Moreover, the grain size distribution is the same between the FFS/RI mudflats and the BERA mudflats. See Figure 1-a in the October 10, 2009, Benthic QAPP (Windward 2009b) and in both QAPP addenda from 2010 (Windward 2010a, b) as examples. See grain size distribution from the Region 2 FFS (Louis Berger et al. 2014) (same as in the LPRSA mudflats for the BERA). Also see the presentation given to Region 2 by CPG on March 6, 2014.	See CPG response to Comment No. 24, which appears to be inconsistent with this response. The revised document will be reviewed to confirm that EPA's comment has been addressed appropriately.



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167	Appendix A - SLERA, Pages 16-17, Sections 2.1.1 and 2.1.2	In Sections 2.1.1, Sediment Data, and 2.1.2, Surface Water Data, it is unclear what screening values will be used to evaluate the sediment and water between RMs 4 and 8 (p.16, second sentence of second to last paragraph, and p. 17, last paragraph, respectively). In Section 3.2.1, Tissue, Sediment, and Surface Water (first paragraph, last sentence), it is stated that marine values were used for RMs 0-8 and freshwater values were used for RMs 4-17.4. In the SLERA, areas that transition between fresh and salt water should be screened against the lower of fresh and marine thresholds.	Comment can be incorporated into revised document.	The revised document will be reviewed to confirm that EPA's comment has been addressed appropriately.
168	Appendix A - SLERA, Page 18, Section 2.1.3	In Section 2.1.3, clarify why no surface water samples are included for RMs 12-17.4. Table 2-2, Number of Surface Water Samples, should be revised using all available data.	Region 2 and its reviewers should be aware that no surface water samples were collected above RM 10.2 other than background samples above Dundee Dam, consistent with Region 2-approved surface water QAPPs. Text can be added to the revised BERA to reiterate this for Region 2's benefit.	Acceptable.
169	Appendix A - SLERA, Page 18, Table 2-2	The table indicates that 2 surface water samples were collected between RM 8 and RM 10. According to the SV-CWCM summary report, no samples were collected between these RMs. Please revise the text and table accordingly.	There are two samples identified as RM 9 collected during the CWCM low-flow event (2012). The station description is "RM 4.5-9.0 (Tidal river 1 for LF Event)."	The text and table should be revised to reflect this fact.
170	Appendix A - SLERA, Page 19, Table 3-2	Table 3-2, Summary of Fish and Invertebrate Tissue Used in SLERA, should be labeled, "Table 2-3."	Comment can be incorporated into revised document	Acceptable.
171	Appendix A - SLERA, Page 20, Table 3-2	Table 3-2 [sic] in Section 2.1.3, Tissue Data, footnotes "h" and "i" inappropriately state that American eel tissue data and carp tissue data, respectively, will only be evaluated in the Human Health Risk Assessment; American eel and carp tissue must both be included in the Ecological Risk Assessment.	See response to General Comment No. 3. Carp were not included as representative fish in the Region 2-approved PFD.  In the revised BERA, carp and other large fish will be evaluated as part of the uncertainty assessment as possible prey in the mammalian diet. Carp will not be fed to the avian receptors since it is not ecologically relevant, although the evaluation of medium-sized fish (see Table 2 attached) will be evaluated as part of the uncertainty assessment as possible prey in heron and kingfisher diets.	See previous comments regarding inclusion of carp. The memorandum "Revised Sample Analysis Plan for Catfish/Bullhead, Carp, Bass, White Sucker, and Northern Pike Tissue for the Lower Passaic River Restoration Project (Revised Fish Sample Analysis Plan, Part 1)" dated May 21, 2010 specifically indicates that carp will be evaluated in the BERA and identifies that carp were included as an alternate species. CPG must make the changes as directed by EPA regarding evaluating carp in the BERA.
172	Appendix A - SLERA, Pages 23-26, Section 3 and Figures 3-1 through 3-3	<p>The methods that are described in Section 3, Screening Methods, and summarized in Figures 3-1, Surface Sediment COPEC Screening Process; 3-2, Surface Water COPEC Screening Process; and 3-3, Tissue COPEC Screening Process, for identifying COPECs are not appropriate. Specifically:</p> <p>Contaminants (in sediment, water, or tissue) cannot be eliminated if they are not detected in any sample unless the available non-detect data for each COI is first compared to the selected TSV. If the detection limit is greater than the selected TSV, the contaminant cannot be excluded.</p> <p>Frequency of detection should not be used as a criterion for retaining or eliminating contaminants in the SLERA.</p> <p>The spatial distribution of detected contaminant concentrations should not be used to reduce or eliminate contaminants in the SLERA.</p> <p>The lack of a TSV should not be used to identify contaminants that need to be discussed in the uncertainty section of the BERA; those contaminants should be retained and evaluated in the BERA. If a TRV cannot be identified or derived during the BERA evaluation, then such COPECs need to be discussed in the uncertainty section of the BERA.</p>	<p>The CPG disagrees with Region 2's contention that the COPEC screening process is inappropriate. This comment directs CPG to take an approach inconsistent with previous agreements and documentation. COPEC screening flowcharts were presented in Appendix A of the RARC Plan (Windward and AECOM 2013), which underwent multiple reviews and comments by Region 2. See Sections 2.1-2.3 and Figures 2-1 and 2-2 in Appendix A of the RARC Plan (Windward and AECOM 2013). Region 2 did not provide additional changes/edits to these figures based on multiple rounds of review.</p> <p>The last round of Region 2 comments on the RARC Plan and Appendices (1/31/2014) only had three comments regarding Appendix A: an editorial change, the removal of the word "urban," and the clarification that TRVs would be submitted with the BERA.</p>	<p>As stated in EPA's 6/19/2015 letter to the CPG:</p> <p>Appendix A of the October 2013 RARC specifies the Chemicals of Potential Ecological Concern (COPEC) selection process for the BERA, but Comment 172 relates to the SLERA. As we have discussed, the SLERA should take a much more inclusive/conservative approach than the BERA and thus the requested modifications to the screening process are appropriate for the SLERA. At a minimum, frequency of detection should not be used as a criterion for eliminating contaminants in the SLERA.</p> <p>The changes directed by EPA in this comment must be made.</p>

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173	Appendix A - SLERA, Page 24, Figure 3-2	There appears to be a typo in Figure 3-2. Tissue samples are referenced. Please clarify.	Comment can be incorporated into revised document.	Acceptable.
174 <sup>2</sup>	Appendix A - SLERA, Page 26, Section 3.1; Page 56, Section 4.2.2; and Attachment A3, page 13	<p>For fish and invertebrate whole body tissue, metals (other than mercury, methyl mercury, selenium, and butyltins) were immediately culled from the SLERA/BERA without being identified as whole-body tissue COIs and without screening.</p> <p>Additionally, PAHs were not identified as whole body tissue COIs for fish. The rationale is presented on p.13 of Attachment A3 and pp. 26 and 56 of the SLERA, and is based on regulation/metabolism by invertebrates and fish of these contaminant classes.</p> <p>The bioaccumulative nature of inorganics is addressed in EPA 2000, Table 4-2, which states the following metals are considered important bioaccumulative compounds: Arsenic, Cadmium, Chromium VI, Copper, Lead, Methyl Mercury, Nickel, Selenium, Silver, and Zinc. The fact that tissue residue effects levels are available for metals further validate the need for appropriate screening, and conservative tissue TRVs should be selected.</p> <p>PAHs should remain as a COI if present in adult whole body tissue and evaluated using appropriate CBRs. In addition, unmeasured ecotoxic PAH metabolites are expected to be present and contributing to body burden. Therefore, adverse effects from PAHs and their metabolites to adult and early life stage fish should be further discussed in the uncertainty section.</p>	<p>The CPG disagrees with Region 2's comments. Dietary pathway and chemicals were discussed in the Region 2-approved PFD (Windward and AECOM 2009) and in the RARC Plan (Windward and AECOM 2013). The limitation of the fish dietary evaluation to just metals and PAHs is consistent with the Region 2-approved PFD (Windward and AECOM 2009) and the RARC Plan (Windward and AECOM 2013).</p> <p>See footnote "e" to PFD Table 5-2 (Windward and AECOM 2009) and the same language as in the PFD under footnote "d" of Table 2-2. The PFD went through multiple rounds of review by Region 2 and was approved on July 31, 2009.</p> <p>Section 2.3 of the RARC Plan (Windward and AECOM 2013) addresses the rationale for excluding some metals and PAHs for whole-body fish and invertebrates without screening.</p>	The PFD and RARC plan provide information to be used in the BERA. This comment is focused specifically on the SLERA. As EPA and the CPG discussed on 5/14/2015, the SLERA is a stand-alone document and conservative in nature. The changes directed by EPA in this comment must be made. In the SLERA, screen all compounds using residue (whole body) TRVs vs. whole body concentrations, with TRVs being NOAELs.
175	Appendix A - SLERA, Page 26, Figure 3-4	A reference for footnote a on Figure 3-4 needs to be provided.	Comment can be incorporated into revised document.	Acceptable.
176	Appendix A - SLERA, Page 27, Section 3.1, first paragraph, last sentence	Please clarify why dietary LOE was used instead of tissue LOE. Tissue LOE should be used for all compounds detected.	See response to Specific Comment No. 174.	Please see response to Comment No. 174.
177	Appendix A - SLERA, Page 27, Section 3.1	Dietary COIs for fish are limited to metals and PAHs (i.e., those contaminants that the SLERA states could not reliably be assessed through the screening of tissue residues). Fish tissue residues and dietary exposure represent discrete risk questions/lines of evidence and each must be evaluated for all COIs via separate Assessment and Measurement Endpoints. All prey tissue COIs (not limited to metals and PAHs) should be used for dose estimations for corresponding fish feeding guilds and screened against conservative NOAEL dose-based TRVs.	See response to Specific Comment No. 174.	Please see response to Comment No. 174.
178	Appendix A - SLERA, Page 29, first bullet	At the top of the page, please clarify why the concentration in surface water is listed as being from RM 8 to RM 17.4.	The CPG notes for Region 2's benefit that surface water included in a drinking water pathway was limited to freshwater only. The BERA defined > RM 8 as freshwater (see Section 8.1.2.3).	See previous comment on this issue.

<sup>2</sup> Comments 161, 176, 177, and 201 also relate to this issue. Dietary pathway and chemicals were discussed in the EPA approved PFD (Windward and AECOM 2009) and in the RARC Plan (Windward and AECOM 2013). The limitation of the fish dietary evaluation to just metals and PAHs is consistent with the EPA approved PFD and the RARC Plan.

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179	Appendix A - SLERA, Page 29, Table 3-1	<p>The average value for eel weight is listed as 0.052 kg. Considering that many juvenile eels were caught in the northern portion of the LPRSA, these juveniles may skew the population size downward (i.e. the average weight of the eels caught in the October 2012 sampling effort was 0.2192 kg, an order of magnitude greater than the overall reported average).</p> <p>Therefore, eels should be separated into two classes: juvenile and adult, with each having their own average weight, etc.</p>	While only one size of eel was evaluated in the SLERA, two sizes of eel were evaluated in the BERA (see Section 7.2.2.2 of the BERA). The evaluation of smaller eel is more conservative than the evaluation of larger eel (see HQs in Table 7-21 of the BERA).	The RARC plan provides information to be used in the BERA. This comment is focused specifically on the SLERA. As EPA and the CPG discussed on 5/14/2015, the SLERA is a stand-alone document and conservative in nature. The changes directed by EPA in this comment must be made.
180a	Appendix A - SLERA, Page 29, Table 3-1	The type of dietary exposure calculations identified for each focal species (Table 3-1, Sources of Dietary Dose Exposure Parameter Data) would normally be conducted in the BERA rather than the SLERA (but with less conservative EPCs); the rationale for conducting this type of detailed screening is not provided, but should be presented so that the reader understands why the screen is being conducted at the focal species level.	<p>The CPG notes for Region 2's benefit that in Appendix A of the RARC Plan, "Screening-level values are medium and receptor group specific. The result is a set of COPEC-receptor pairs to be evaluated in the BERA." Region 2 did not comment on this in its multiple reviews of the RARC Plan and Appendices.</p> <p>As discussed with Region 2 in the May and June 2015 Region 2-CPG teleconference calls, the SLERA will screen by species, but if any chemicals come through for any species in a given media, those chemicals will be evaluated for all species for that media in the BERA.</p>	Acceptable.
180b	Appendix A - SLERA, Page 29, Table 3-1	The use of average values (Table 3-1) is not appropriate in the SLERA; the purpose of the SLERA is to use values that will result in the highest likelihood of capturing potential effects.	The CPG disagrees with Region 2's contention that CPG's approach is not appropriate. The ingestion rate is a factor of body weight, so changing the body weight will change the ingestion rate as well; not change risk results.	Average values should not be used in the SLERA. The CPG must make this change as directed by EPA.
181	Appendix A - SLERA, Pages 31-32, Section 3.2.2.2 and Table 3-2	<p>Prey composition of receptors ingesting invertebrates as described in Section 3.2.2.2, Prey Composition, and in Table 3-2, Prey Types Evaluated in the Dietary Dose for Each Receptor, relies on existing data from the river (worms, crabs, etc.).</p> <p>Assuming that the diet of mummichog and other invertivorous fish is comprised of worms alone may underestimate exposure. Grass shrimp, amphipods, and other invertebrates that make up the majority of the diet of invertivorous fish may contain higher concentrations of some contaminants than worms. This issue should be discussed with regards to potentially under-estimating the risk in the uncertainty section.</p>	Empirical invertebrate prey data are only available for worms and blue crab, so the dietary estimate will stay as 100% worms for mummichog. The uncertainty will be discussed in the revised SLERA and is already discussed as part of the BERA (see Section 7.2.4.2 of the BERA).	Acceptable. Please include the expected/likely diet of invertivorous fish in this discussion.
182	Appendix A - SLERA, Page 32, Equation 3-3	The following equation is used for the estimation of fish egg concentration is $C_{egg} = C_{adult} \div CF$ (aka BMF). Please provide the basis of the BMF calculation so that the appropriateness of this formula can be assessed.	The basis of the CFs are presented in Table 3-3 of the SLERA and are expressed as the adult-to-egg ratio, where $CF = C_{adult}/C_{egg}$ .	Acceptable.
183	Appendix A - SLERA, Pages 32-34, Section 3.2.3	No COPEC-receptor pairs should be screened out in the SLERA based on egg tissue concentrations. Mummichog egg tissue COPEC concentrations were estimated using inappropriate adult-to-egg conversion factors and an unsubstantiated estimate for egg hardening. For PCBs, PCDDs/PCDFs and OC Pesticides, more appropriate CFs based on multiple species and more data are available in Russell et al. (1999) rather than Niimi (1983) and Tietge et al. (1998). For mercury, egg concentration is related to maternal diet so it is not appropriate to use any conversion factor. There is uncertainty that conversion factors that are not validated using data on mummichog or evaluated using lipid data for adults and eggs would result in reasonable egg tissue concentrations. No basis is provided for the 2-3 fold increase in weight of unfertilized eggs due to hardening in the reference provided; rather Lahnsteiner (2000) shows weight increase during hardening of only about 22% of egg weight for rainbow trout.	The papers suggested by Region 2 (Russel et al. [1999] and Lahnsteiner [2000]) will be evaluated. It should be noted that the approach used in the SLERA for modeling PCB concentrations in fish eggs was refined in the BERA, where a regression approach was used (rather than a CF), so changes in the CFs used in the SLERA will not affect the egg modeling approach used in the BERA.	Acceptable.

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184	Appendix A - SLERA, Page 34, Table 3-4	Higher avian biomagnification factors (BMFs) for mercury than those presented in Table 3-4, Avian BMFs, can be calculated using data from other sources (Atwell et al. 1998; Bargagli et al. 1998). In the absence of site-specific data to validate the assumed avian BMF for mercury, mercury should not be screened out in the SLERA based on estimated bird egg concentrations.	The derivation of and resulting BMF are determined based on the strength of the study and scientific rigor of the evaluation. It is not appropriate to choose a value just because it “is higher”. The papers suggested by Region 2 (Atwell et al. [1998]; Bargagli et al. [1998]) were evaluated. The data from Bargagli et al. (1998) only includes BMFs based on fish muscle (not fish WB which is being applied at the LPRSA) and this paper supports a mercury BMF of approximately 1, which is what was used in the SLERA. No bird egg tissue concentrations were reported in Atwell et al. (1998) (bird adult tissue were reported), so it is unclear how BMFs could be derived from this study.	Acceptable.
185	Appendix A - SLERA, Page 34, Section 3.3	According to the information presented in Section 3.3, the SLERA “TRVs” (which would more clearly be called toxicity screening values [TSV] to distinguish them from the TRVs used in the BERA) are presented in Attachment A3. However, this attachment does not appear to be complete. The USEPA-recommended TRV tables are included in Supplement A3-1 and the TRV working database is presented in Supplement A3-2. However, the list of TRVs for water, sediment, and tissues that were used in the SLERA does not appear to be presented in Attachment A3. A series of tables that present the SLERA TRVs (TSVs) that were used in the assessment needs to be included in the document along with the rationale for their selection that describes a hierarchical approach to the selection of SLERA TRVs (TSVs).	The CPG notes for the Region’s benefit that screening level values are all presented in Attachment 3 (TRV deliverable) of Appendix A (SLERA).	EPA expects the ability for the reader to find the SLERA values and BERA values that were used in each evaluation will be clear and transparent. It is not clear from this response that this will be done. The revised document will be reviewed to confirm that EPA’s comment has been addressed appropriately.
186	Appendix A - SLERA, Page 35, Section 3.4	At no point in the SLERA is there any mention that sediment data used in the screening evaluation were normalized to organic carbon content. Instead, the SLERA text refers readers to Attachment A2, which presents the HQs calculated for each LOE and states that the results were normalized. At the SLERA stage, OC-normalized data should not be used in the refinement of COPECs, and use of these data for the BERA is even questionable. The SLERA should be revised to reflect the evaluation of non-OC-normalized data, and those results should be carried forward in the BERA.	OC-normalization is necessary in some cases for the comparison of sediment thresholds to NJDEP sediment screening thresholds. The comparison of dry weight sediment concentrations to OC-normalized thresholds is inaccurate and inappropriate.  In addition, ERAGS (USEPA 1998) does not indicate that OC-normalization should not be done in a SLERA, however the first mention of OC is in the fate and transport section of the BERA subsection.	SLERA data should not be OC-normalized except where OC-normalized NJDEP sediment ESLs are selected for screening. BERA sediment data should not be OC-normalized except where selected sediment effects values or TRVs are OC-normalized. In those cases, sediment data should be presented as both non-normalized and OC-normalized.
187a	Appendix A - SLERA, Page 37, Table 4-1	Aroclor 1268 has an ‘a’ footnote. This footnote pertains to metals. Clarification is needed.	Comment can be incorporated into revised document.	Acceptable.
187b	Appendix A - SLERA, Page 37, Table 4-1	In addition to the listed, individual, PCDDs/PCDFs (i.e., the 17 World Health Organization [WHO] congeners assigned Toxicity Equivalence Factors [TEFs]), sediment should also be evaluated on the basis of the PCDDs/PCDF mixture, commonly referred to as the dioxin (TCDD) toxicity equivalence (TCDD-TEQ) of a sample. This represents the sum of adjusted dioxin/furan congener concentrations using congener-specific TEFs. In addition for use in tissue, this approach is also used to generally characterize sediment potential toxicity because chlorinated dioxins and furans are typically found as a mixture comprised of similar congeners (structure and related toxicity), and these are assessed in relation to 2,3,7,8- TCDD, the most studied, and considered the most toxic congener, of this group.	The CPG disagrees with this comment; the use of a TEQ approach for invertebrates is not appropriate or scientifically defensible. As stated in Appendix A, Attachment 3, the TEQ screening-level TRVs for PCDDs/PCDFs and coplanar dioxin-like PCBs were not derived for benthic invertebrates because there is limited evidence for ligand activation of the Ah (dioxin) cellular receptor in these organisms and, as such, they are not susceptible to the dioxin-like effects reported for vertebrates (e.g., fish) (Van den Berg et al. 1998). Thus, the evaluation of PCDDs/PCDFs and PCBs using a TEQ approach is not appropriate for evaluating the toxicity of invertebrates. In fact, toxic equivalency factors (TEFs) are available only for fish, birds, and mammals.  No change will be made to the document.	EPA agrees that using TEFs for sediments, although associated with some uncertainty, could yield useful insight at the SLERA stage of the ERA process. We agree that the uncertainties of using TEFs for sediment are too high for use in the BERA. Please generate TEQ values using the fish TEFs as directed in the original comment for use in the SLERA.
188a	Appendix A - SLERA, Page 40, Table 4-2	PCDDs/PCDFs lists 2,3,7,8-TCDD; however, the TEQ (sum) is not listed. Sediment should also be evaluated for dioxin TEQ (as explained above).	The use of a TEQ approach for invertebrates is not appropriate or scientifically defensible. See comment response above (Comment 187b).	See response for comment 187b.

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188b	Appendix A - SLERA, Page 40, Table 4-2	Alpha-BHC and beta-BHC have a 'c' footnote. This footnote pertains to PCBs. Clarification is needed.	Comment can be incorporated into revised document.	Acceptable.
189s	Appendix A - SLERA, Page 44, Table 4-5	There is a footnote 'a' pertaining to chlordane; however this footnote is not used in the table. Clarification is needed.	Comment can be incorporated into revised document.	Acceptable.
189b	Appendix A - SLERA, Page 44, Table 4-5	Additionally, as per NJDEP's EETG section 5.4, the investigator is not precluded from proposing sediment ESC for contaminants without an ESC on the NJDEP table. Contaminants with high frequency of detection but lacking ESC should be carried through the risk assessment process.	The CPG notes for the Region's benefit that COIs with no TRVs were discussed in the SLERA for each LOE evaluated. This discussion will be moved to/repeated in the appropriate uncertainty discussion sections of the revised BERA.	The revised document will be reviewed to confirm that EPA's comment has been addressed appropriately.
190	Appendix A - SLERA, Page 45, Section 4.1.2	It is not clear why dissolved and total concentrations were screened for some metals, while only dissolved concentrations were screened for other metals; all of the data for metals in surface water (i.e., total and dissolved concentrations) should be screened to identify the COPECs that need to be evaluated in the BERA.	The basis of the surface water concentration for screening is determined by the basis of the surface water screening value (i.e., some criteria are based on a dissolved basis and some criteria are based on a total basis).	The rationale provided is appropriate for the BERA; however, for the SLERA, total concentrations should be used for screening purposes.
191	Appendix A - SLERA, Page 45, Section 4.1.2	Screening-level TRVs are available for total metals in freshwater and in marine waters (e.g., CCME water quality guidelines). Alternative screening-level TRVs should be used when EPA water quality criteria are not available for contaminants in freshwater or marine waters.	The CPG notes for the Region's benefit that the current surface water thresholds were selected using the hierarchy presented in Section 4.2 of the Appendix A, Attachment 3; this hierarchy is as follows: 1) NJDEP, 2) EPA AWQC, and 3) ORNL Tier II values.	See response to Comment No. 148. The revised document will be reviewed to confirm that EPA's comment has been addressed appropriately.
192	Appendix A - SLERA, Page 46, Table 4-6	PCDDs/PCDFs list the 17 WHO dioxin and furan congeners; however, the TEQ (sum) is not listed. Surface water should also be evaluated for dioxin TEQ.	The CPG disagrees with this comment; the use of a TEQ approach for invertebrates is not appropriate or scientifically defensible. See previous comment response (Comment 187b).  No change to the document.	See response to Comment No. 187b.
193	Appendix A - SLERA, Pages 47-48, Table 4-7	Several chemicals are excluded from further evaluation due to a lack of marine screening levels. It is recommended that surrogate values be used in the absence of marine screening levels, even if they are freshwater values. In addition, it is unclear why those chemicals shown in Table 4-7 as having no screening value are not the same as those shown in Table 4-8. Please revise the tables and make the necessary corrections.	Available FW or marine values will be used as a surrogate and the uncertainty with applying such values for screening will be discussed in the uncertainty section in the revised BERA.	Acceptable.
194	Appendix A - SLERA, Page 48, Table 4-7	PCDDs/PCDFs lists 2,3,7,8-TCDD; however, the TEQ (sum) is not listed. Surface water should also be evaluated for dioxin TEQ.	The CPG disagrees with this comment; the use of a TEQ approach for invertebrates is not appropriate or scientifically defensible. See previous comment response (Comment 187b).  No change to the document.	See response to Comment No. 187b.
195	Appendix A - SLERA, Page 49, Section 4.1.2	Bullet PCDDs/PCDFs rules out all but 2,3,7,8-TCDD due to lack of surface water thresholds; however, the TEQ (sum) should also be evaluated for dioxin.	The CPG disagrees with this comment; the use of a TEQ approach for invertebrates is not appropriate or scientifically defensible. See previous comment response (Comment 187b).  No change to the document.	See response to Comment No. 187b.
196	Appendix A - SLERA, Page 50, Table 4-8	Surface water contaminants cannot be eliminated during the SLERA based on the lack of a screening-level TRV; contaminants listed in Table 4-8 must be included as COPECs for evaluation in the BERA.	The CPG notes for the Region's benefit that COIs with no TRVs were discussed in the SLERA for each LOE evaluated. This discussion will be moved to/repeated in the appropriate uncertainty discussion sections of the revised BERA.	The revised document will be reviewed to confirm that EPA's comment has been addressed appropriately.

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197a	Appendix A - SLERA, Page 50, Table 4-8	PCDDs/PCDFs list the 17 WHO dioxin and furan congeners; however, the TEQ (sum) is not listed. Surface water should be also be evaluated for dioxin TEQ.	The CPG disagrees with this comment; the use of a TEQ approach for invertebrates is not appropriate or scientifically defensible. See previous comment response (Comment 187b).  No change to the document.	See response to Comment No. 187b.
197b	Appendix A - SLERA, Page 50, Table 4-8	Additionally, as per NJDEP's EETG section 5.4, the investigator is not precluded from proposing surface water ESC for contaminants without an ESC on the NJDEP table. For example, it is stated (p. 49) that cis-1,2 dichloroethylene is present in 96% of surface water samples, but is culled from the SLERA due to lack of ascreening criterion or standard. Contaminants with high frequency of detection but lacking ESC should be carried through the risk assessment process.	The CPG notes for the Region's benefit that COIs with no TRVs were discussed in the SLERA for each LOE evaluated. This discussion can be moved to/repeated in the appropriate uncertainty discussion sections of the revised BERA.	The revised document will be reviewed to confirm that EPA's comment has been addressed appropriately.
198	Appendix A - SLERA, Page 52, Table 4-9	PCDDs/PCDFs list individual dioxins and furans; however, the TEQ (sum) is not listed. Invertebrate tissue should be evaluated for dioxin TEQ.	The CPG disagrees with this comment; the use of a TEQ approach for invertebrates is not appropriate or scientifically defensible. See previous comment response (Comment 187b).  No change to the document.	See response to Comment No. 187b.
199	Appendix A - SLERA, Page 56, Section 4.2.1	The document lists estuarine water from RM 0-8 and freshwater from RM 4-17.4. This is inconsistent. Clarification is needed.	This comment will be incorporated into the revised document.	Acceptable.
200	Appendix A - SLERA, Page 63, Table 4-13	The white sucker LOAEL has a 'b' footnote for total PCBs; however, footnote 'b' pertains to NOAEL. Clarification is needed.	This comment will be incorporated into the revised document.	Acceptable.
201	Appendix A - SLERA, Page 66, Section 4.2.3; Attachment 3, Page 45, Section 5.3, Fish Diet	Dietary COIs are limited to metals and PAHs, i.e., those contaminants that the SLERA states could not reliably be assessed through the screening of tissue residues. Fish tissue residues and dietary exposure represent discrete risk questions/lines of evidence and each must be evaluated for all COIs via separate Assessment and Measurement Endpoints. All prey tissue COIs (not limited to metals and PAHs) should be used for dose estimations for corresponding fish feeding guilds and screened against conservative NOAEL dose-based TRVs.	See response to Specific Comment No. 174.	Please see response to Comment No. 174.
202	Appendix A - SLERA, Page 70, Table 4-17	Table 4-17 should show screening values, screening concentration and HQs, not just an "x" in a box (for all media).	Attachment A2 of the SLERA already presents screening values, screening concentrations and HQs. Note that there are 14 tables showing the screening comparisons. Some tables have over 900 cells populated in the table (e.g., fish tissue) and over 13,000 cells are populated throughout all of the tables in Attachment A2. Due to the vast amount of data presented in these tables, it is not practical to include as tables in the main text, other than as summary tables.  Furthermore, it is unclear how the addition of screening values, concentrations, and HQs to screening summary table will help with clarity and are warranted for a SLERA when the purpose of the SLERA is to identify which COPECs should be retained for further evaluation and which chemicals need no further evaluation. The magnitude of exceedances is not relevant for the purposes of the SLERA.  Table 4-17 of Appendix A is intended to summarize the indicated data in the most succinct way. HQ values, max concentrations, and screening values are all presented in Attachments. For the purpose of guiding the reader from the SLERA to the BERA, a matrix of 'x's should suffice.	EPA has indicated in other responses that additional clarity is needed to present the summary of risks in both the SLERA and BERA. A matrix of Xs is not sufficient for EPA.

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203	Appendix A - SLERA, Page 70, Table 4-17	The table indicates an exceedance of the LOAEL for total TEQs in the belted kingfisher model. Review of Attachment A2 indicates an HQ of 0.89. Please revise accordingly.	This comment will be incorporated into the revised document. Any discrepancies will be reconciled.	Acceptable.
204	Appendix A - SLERA, Page 74, Section 4.4	All fish sizes should be used for the SLERA.	See response to General Comment No. 3.	See previous responses regarding inclusion and evaluation of all fish data. The memorandum "Revised Sample Analysis Plan for Catfish/Bullhead, Carp, Bass, White Sucker, and Northern Pike Tissue for the Lower Passaic River Restoration Project (Revised Fish Sample Analysis Plan, Part 1)" dated May 21, 2010 specifically indicates that carp will be evaluated in the BERA, and therefore in the SLERA, and identifies that carp were included as an alternate species. CPG will follow the comments submitted by EPA regarding evaluating carp in the BERA and SLERA.
205	Appendix A - SLERA, Page 77, Section 4.6	The document states that reptiles are only expected in freshwater portions of the river; however, turtles would be expected in the lower four miles of the LPRSA. Reptiles should be added to the estuarine portion of the river.	<p>The CPG disagrees that reptiles will be found in the lower 4 miles of the LPRSA. There is a low likelihood for encountering reptiles in the estuarine portion of the LPRSA given the poor quality of turtle habitat there and in the surrounding region, and we have seen no evidence to suggest otherwise. Reptiles were only spotted during surveys of freshwater portions of the LPRSA and above Dundee Dam. Anecdotal evidence present online also suggests that reptiles are present upstream of the LPRSA.</p> <p>In addition, this comment directs CPG to take an approach inconsistent with Region 2's own FFS ERA Appendix D Section 4.1.3, page 4-15 (Louis Berger et al. 2014).Region 2 stated in the FFS ERA that "the presence of amphibians and reptiles is not well documented in the FFS Study Area and there appears to be little viable habitat to support this ecological group."</p> <p>Region 2 is requested to provide documentation and citations to support this comment. Otherwise, no change will be made to the document</p>	Not observing a receptor is insufficient evidence to eliminate a receptor or receptor group. If there is potential for sea turtles to occur in the lower 4 miles, then sea turtles should be considered potential receptors. Identification of potential species that could be found in the LPRSA is warranted. Sea turtles could access the LPRSA although it is unlikely that the LPRSA provides adequate habitat or conditions to support this ecological receptor group. The following text should be added: "Several species of sea turtles could be found in the NY/NJ Harbor estuary, which is near the LPRSA. While it is unlikely that sea turtles would spend significant time in the LPRSA, they may be infrequent visitors, although the LPRSA would not provide adequate habitat or conditions to support this ecological group."
206	Appendix A - SLERA, Page 87, Section 6	Dioxin is not listed for benthic invertebrate tissue or fish dietary dose. Dioxin has been inappropriately culled from the SLERA for these receptors/exposure pathway and must be evaluated for both.	<p>The CPG disagrees with the Region's contention that "dioxin has been inappropriately culled from the SLERA for these receptors..."</p> <p>Based on the data presented in Appendix A, Attachment A2, it can be seen that HQ values for 2,3,7,8-TCDD were in all cases &lt; 1 for benthic tissue. The use of a TEQ approach for invertebrates is not appropriate or scientifically defensible. See previous comment response (Comment 187b). For fish, dioxin (TEQs) were evaluated as part of the tissue residue approach since that is the best method for assessing exposure and potential risk (rather than through the use of a fish dietary model). See previous comment responses.</p>	See response to Comment No. 187b.
207a	Appendix A - SLERA, Page 87, Section 6, first bullet	The text indicates that 11 OC pesticides were retained as COPECs for benthic invertebrates. Table 4-2 shows 14 and Table 6-1 shows 12. Please revise to ensure consistency.	This comment will be incorporated into the revised document.	Acceptable.
207b	Appendix A - SLERA, Page 87, Section 6, first bullet	The text also states that PCB TEQs, PCDD/PCDF TEQs, and total TEQs were retained as COPECs; however, they are not included in Table 6-1. Please revise the text and table to ensure consistency.	<p>The CPG disagrees with this comment; the use of a TEQ approach for invertebrates is not appropriate or scientifically defensible. See previous comment response (Comment 187b).</p> <p>No change to the document.</p>	See response to Comment No. 187b.
208	Appendix A - SLERA, Attachments A1 and A2	The detailed exposure assessment for surface water and tissues that is presented in Attachment A1 was not reviewed to determine if the maximum reported contaminant concentrations matched the results presented in Attachment A2, but based on the number of deviations that were noted for sediment, Attachments A1 and A2 need to be reviewed and evaluated to ensure that the correct EPCs are used in the SLERA.	The CPG is troubled by the fact that the Region had the BERA for over 10 months and did not complete a comprehensive and thorough review of the document consistent with its oversight obligations.	Given the significant issues identified in the BERA it is evident that the SLERA would require significant revisions. In this instance, EPA has chosen to simply identify those sections that would require revision based on comments in the BERA.

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209	Appendix A - SLERA, Attachment A2	Amphibian-specific TRVs are presented in Attachment A2 (COPEC screening tables). There is no reason to include amphibian-specific TRVs in the SLERA; an evaluation of risks to amphibians should be included in the BERA. The amphibian-specific screen needs to be removed from the SLERA.	Amphibians are evaluated with all other receptors of interest for the sake of completeness and to provide a receptor-relevant analysis.	Acceptable.
210	Appendix A - SLERA, Attachment A2	The tables presented in Attachment A2 need titles.	This comment will be incorporated into the revised document.	Acceptable.
211a	Appendix A - SLERA, Attachment A2	The results of the sediment screen are presented in Attachment A2 of the SLERA but the maximum concentrations of contaminants in these tables do not always agree with the summary tables presented in Attachment A1. Please review for consistency and revise as appropriate.	This comment will be incorporated into the revised document. Any discrepancies will be reconciled.	Acceptable.
211b	Appendix A - SLERA, Attachment A2	Note that Table 4-2 cannot be used as a basis for identifying the sediment COPECs for benthic invertebrates that need to be evaluated in the BERA.	No change. It is unclear why Table 4-2 is an unacceptable presentation of COPECs for the BERA; the purpose of that table is to summarize the results presented in Attachments.	Upon further consideration the EPA is willing to withdraw this comment and accept the CPGs response of no action.
212	Appendix A - SLERA, Attachment A3, Page 8	The text under TRV acceptability criteria, second bullet, states that TRVs should represent “NOAEL and/or LOAEL concentrations or doses.” As per ERAGs, section 1.3.1, screening ecotoxicity values should represent a NOAEL for chronic exposures to contaminants to ensure that risk is not underestimated. TRVs used in the SLERA should be reevaluated/revised as appropriate.	NOAELs were used when available from the same study as the LOAEL following the criteria established in the RARC and TRV Memorandum.	The RARC plan provides information to be used in the BERA. This comment is focused specifically on the SLERA. As EPA and the CPG discussed on 5/14/2015, the SLERA is a stand-alone document and conservative in nature. The changes directed by EPA in this comment must be made. The most conservative values should be used in the SLERA.
213	Appendix A - SLERA, Attachment A3, Page 9	The text under TRV acceptability criteria, second bullet, states that avian TRVs based on domesticated species, such as chickens or Japanese quail, will not be used (unless no other data are available). This approach is unacceptable because use of the most conservative NOAEL available is appropriate in a SLERA. TRVs used in the SLERA should be reevaluated/revised as appropriate.	Region 2 has not provided citations for studies showing wild bird species are as sensitive or more sensitive to PCBs as chicken and we are unaware of any such studies. Relevant citations are requested	See previous comments regarding avian TRVs and use of chicken TRVs for evaluating dioxin-like effects in birds, and the distinction between what is appropriate for the SLERA (as opposed to the BERA). The most conservative values should be used in the SLERA.
214	Appendix A - SLERA, Attachment A3, Page 10	Text states that if no NOAEL is available from the same study from which the LOAEL was obtained, no screening level NOAEL was selected. As per ERAGS, section 1.3.1, it is standard practice to multiply the LOAEL by 0.1 and use the product as the screening ecotoxicity value. TRVs used in the SLERA should be reevaluated/revised as appropriate.	NOAELs were used when available from the same study as the LOAEL. The CPG requests Region 2 to provide citations for using unbounded NOAELs and extrapolation factors.	A citation was provided: ERAGs Section 1.3.1. The SLERA should use the most conservative values available and NOAELs are the most appropriate values for the SLERA.
215	Appendix B, SRC	Reported sediment toxicity test results in Appendix B are not identified to determine whether they are raw toxicity test results, batch-wise control-normalized toxicity test results, toxicity test results normalized to other control or reference results. As a result, it is not possible to evaluate the appropriateness of the toxicity data used in the Spearman Rank Correlation (SRC) analyses. Please clarify.	All toxicity data shown in Appendix B to the BERA were control-normalized.  The toxicity test data is supplied in an appendix and is part of the sediment toxicity data report delivered to Region 2.	Acceptable as long as this is clearly stated.
216	Appendix B, SRC	The sediment toxicity test growth endpoints need to be included in the SRC analyses in Appendix B (i.e., <i>Hyalella azteca</i> growth and <i>Chironomus dilutus</i> growth).	Biomass was included in Appendix B. The biomass endpoint was the selected growth endpoint. The inclusion of dry weight as well as biomass would be redundant.	Although it may be redundant, EPA would like to see the information reported.
217	Appendix B, SRC	No information is provided regarding the treatment of the SRC results that are below the detection limit making it difficult to reproduce the results.	By converting any p-value result that is < 0.0001 to the phrase “p < 0.0001”, Region 2 should easily be able to reproduce the results.	Upon further consideration the EPA is willing to withdraw this comment and accept the CPGs response of no action.



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218	Appendix B, SRC	The results of a SRC analysis for all of the COPCs vs. all of the COPC groups should be presented to provide a basis for identifying the COPCs and COPC groups that tend to occur together within the LPRSA.	CPG does not agree that this is a valid approach to bivariate analysis. There are currently 55 COPECs analyzed and 10 response variables (toxicity or community metrics), resulting in 550 correlations. At an alpha of 0.05, that corresponds to ~30 false positives without Bonferroni correction. The inclusion of ≥55 additional variables in the correlation analysis would increase the number of correlations to >3,500 correlations, and the predicted number of false positives to ~180. This is a high level of uncertainty and will produce confounding results and will limit interpretability.  CPG will instead use multivariate statistical methods to describe correlations among chemical variables.	Attached is a technical memorandum (SQT Statistical Guidance 12112015.pdf). providing direction on how to address this issue.
219	Appendix B, BICS	The biomass results from the Benthic Macroinvertebrate Community Surveys (BICS) must be presented.  Statistical summaries of the BICS data collected for the LPRSA and Jamaica Bay area, Mullica River area, and areas above Dundee Dam need to be developed and presented (e.g., mean, SD, minimum, maximum, 5th percentile, 10th percentile, 25th percentile, 50th percentile, 75th percentile, 90th percentile, and 95th percentile) to provide an understanding of the basic distributions of the data sets.  Some of the BICS results are reported as less than detection limit (e.g., Station LPRT16B) which does not make sense and needs to be corrected.  Only five BICS endpoints are included in Tables B1-1 through B1-4; rationale is not provided for excluding other BICS endpoints in the SRC analysis.	CPG disagrees with Region 2's comment based on the following:  a. Biomass data were never collected as part of the community surveys. This comment directs CPG to present data that were never collected as part of the RI/FS. Please see the benthic community survey QAPP and data reports (Windward 2014 a, b).  b. CPG does not see the value of including this number of statistical parameters. Most of these data are presented in the main text of the BERA in Tables 6-5 through 6-8. Additional parameters would need to be calculated to achieve the level of detail requested by Region 2 in this comment.  c. Benthic community data were not collected at Station LPRT16B and so this is not an issue of detection limit  d. Only 5 endpoints are addressed on a site-wide basis throughout the BERA. Six endpoints are included in the freshwater portion only, as the Hilsenhoff Biotic Index only applies to freshwater communities. This is stated clearly in the text of the BERA (Section 6.1.1.5).	Upon further consideration the EPA is willing to withdraw this comment and accept the CPGs response of no action.
220	Appendix B	The discussion of the bivariate correlation analysis (page 286) ignores strong correlations observed between individual contaminants and benthic endpoints for both sediment toxicity and benthic community indices. A summary table should be provided that lists the chemical concentration-endpoint pairs that have r-values less than -0.3 emerging from Tables B1-1b through B1-4b. For the benthic community analysis, there was a high degree of correlation of the Shannon-Weiner and Taxa Richness indices with multiple chemicals, including many metals, pesticides, and PCBs and dioxin Site-wide, many chemicals had elevated correlations (< -0.3) with H. azteca survival and biomass (Table 6-19). The Bonferroni correction should not be used, as it greatly increases false negatives for statistical significance. The focus of the analysis should be the individual chemicals with strong correlations with individual endpoints, not the total number of significant correlations site-wide.	This Region 2 comment does not appear to recognize the following facts about statistical analysis: Region 2 must recognize several facts:  1. "Strong correlation" and "high degree of correlation" are subjective and open to interpretation (and argument). For example, the CPG and most professional statisticians would disagree that $ r  = 0.3$ is a defining threshold for a "strong" relationship. That value corresponds to an r-squared value of 0.09 or only 9% of the variance, which the CPG judges to be weak.  2. Without the Bonferroni correction, one would predict ~30 false positives, potentially confounding the analysis. Furthermore, if the CPG includes all COPECs in the correlation (as requested in comment 218), the predicted number of false positives increases to ~180.  3. Defaulting to the r-value as the only metric by which to evaluate correlations will require substantial re-review of the data; for example, identifying leverage and outlier values amongst all correlations (550 to >3,500 different analyses) that influence the level of r. Alone, r is not an appropriate metric (just as p alone is not an appropriate metric).  4. Statistically significant but weak correlations in Appendix B have only limited utility for informing risk management decisions, so they should not be given inappropriate weight as Region 2 requests in their comment.	See response to Comment No. 218.

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221	Appendix D, Pages 10-12, Table 2-1 and Page 26, Section 2.3	Some of the surface water TRVs selected for the draft BERA are linked to severe effect levels, such as the LC50s shown for 2,3,7,8-TCDD and pyrene. Mortality to 50% of the test population is too severe an effect endpoint to serve as an appropriate chronic TRV for the BERA. If no low effect data are available, severe effect levels should be used as a basis for estimating a lower and more appropriate effect level (e.g., LC50/10 or LC50/ACR). The draft BERA essentially follows this recommended approach for butyl benzyl phthalate and cyanide, estimating a chronic TRV using the 5th percentile acute value/ACR (where the acute value is analogous to the LC50). It is unclear why this approach was not applied to TCDD. This comment also applies to lead for amphibian TRVs, where the selected TRV (40 µg/L) is an acute value representing a severe effect endpoint (7-d egg survival LC50).	The CPG did not identify sufficient acute or chronic data for an SSD, which is why the lowest chronic toxicity values for TCDD and pyrene were used. Clarification of the rationale for each chemical will be added to the revised BERA.	Lowest chronic values or lowest acute values can be presented as such, but if the endpoint is 50% mortality, this value should not serve as the selected endpoint. An appropriate chronic value (i.e., one with sublethal effects) can and should be estimated from values linked to severe effects.
222	Appendix F, General	This appendix provides toxicity profile information for only two contaminant categories, that of PCBs and PCDDs/PCDFs. Although these represent significant risk driver chemicals for this project, it is unclear why other prominent contaminants (PAHs, mercury, pesticides, other inorganics, etc.) are not summarized here as well. Please clarify and/or add additional information.	Appendix F is intended to present supplemental information regarding COCs listed in the BERA conclusions (currently Section 13); those include total PCBs, PCDD/PCDFs, total TEQ, and methylmercury. Methylmercury has not been described in Appendix F and should be added for completeness and to address this comment. Otherwise, no additional COPECs need be addressed in Appendix F.	Acceptable.
223a	Appendix F, Section 3	This section was reviewed with a focus on the relationship of chlorinated dioxin and furan toxicity to ecological receptors as obtained through literature reviews over the years. As a result of this review, additional information should be added, as outlined below. Please note, however, that many of the cited studies are also applicable to other key contaminant categories found in the lower Passaic River which are known to be similar to PCDDs/PCDFs, in structure and physical & chemical properties, and therefore, toxicity, such as some forms of PCB and PAH compounds. Therefore, the toxicity information in Section 2, PCBs can be bolstered by many of the reference materials provided below, as applicable. In addition, this supplemental information should be considered for incorporation in Appendix E, TRVs.	No response required for comment 223a	The revised document will be reviewed to confirm that EPA's Comment No. 223 (parts a to e) has been addressed appropriately.
223b	Appendix F, Section 3	Page 2, paragraph 2: Regarding the uptake of dioxins in aquatic systems, in addition to the information presented, this section should assimilate the more recent, site-specific findings by Dr. Rainer Lohmann and his research team (Khairy, M.A., et al., 2014) on dioxin and dioxin-like compounds in Passaic River sediment, pore-water and biota. This work is also applicable to PCBs and PAHs.	This information will be evaluated and if deemed appropriate, incorporated in Appendix F.	Acceptable.
223c	Appendix F, Section 3	Page 2, paragraph 3: In addition to the described toxic effects to fish, this section should be expanded to include more recent findings of important cardio-vascular and other developmental impacts (swim bladder effects) in fish embryos from sub-lethal exposure to dioxin (Chen, J., 2015; Yue, M. S., et al, 2015; Aluru, N., et al., 2015; Park Yj, et al., 2014). In addition, behavioral effects have also been observed in fish as a result of exposure to PCDDs/PCDFs and related compounds, e.g., PCBs and PAHs. (Weis, 2011). A comprehensive, current, summary of fish impacts from Persistent Organic Pollutants (POPs) is found in Organic Chemical Toxicology of Fishes: Volume 33, Fish Physiology, Chapter 2, Johnson L.L. et al. (2014), which should be consulted to upgrade the information on fish toxicity in this section.	This information is not relevant to growth, reproduction, or survival which are the endpoints that are evaluated at the population level in a BERA. Unless Region 2 can provide documentation of this link, these studies will not be added.	The documents cited should be reviewed and relevant information added. It is hard to see how impacts to the cardiovascular system or other developmental effects would not impact growth, reproduction or survival.

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223d	Appendix F, Section 3	Significantly missing from Appendix F, Section 3, are toxic effects to shellfish, especially oysters and crabs. Due to both the importance of these species in this ecosystem and the area-specific studies that have been performed, the findings of toxic effects from dioxin exposure to the Eastern oyster (Wintermyer, M.L., and Cooper, K.R., 2003, 2006 and 2009) and related published research (Wintermyer, et al., 2004), should be incorporated. Similarly, toxic effects from dioxin exposure to crabs (Weis, J.S., et al 2011; Reichmuth, J.M., et al 2009) should also be incorporated.	Documents will be reviewed and relevant information added.	Acceptable.
223e	Appendix F, Section 3	In addition, area-specific avian studies on immunotoxicity and adverse reproductive effects based on exposures to TCDDs and PCBs (Grasman, K.A. et al., 2012) have been conducted involving Herring Gulls and Black-Crowned Night Herons from within the Newark Bay Complex. This important area-specific information should be appropriately incorporated in the BERA.	Documents will be reviewed and relevant information added.  The relevance of these studies are suspect, given that local populations of birds could be exposed to a mixture of contaminants that includes PCBs and TCDD but is not exclusive to either one. It is highly unlikely that causation was established.	Acceptable.
224	Appendix G, Worksheet G11, Aquatic Plants	The TRV for tributyltin is shown as “0.000”. Please revise.	Comment can be incorporated into revised document	Acceptable.
225	Appendix J, Page 6, Section 2.2.1, first paragraph, third sentence	The following statement is made:  <i>“Sediment chemistry data from the estuarine regional areas that were not co-located with toxicity data were not compiled, and are not included in the background dataset.”</i>  This approach is inappropriate. Sediment chemistry data collected from background areas should be used regardless of whether it was co-located with toxicity data. Please revise the text and the background dataset accordingly.	It is more appropriate to use only paired data, given that we can identify reference locations at which toxicity was high and eliminate those from the reference area dataset. The inclusion of chemistry data without toxicity data could therefore bias the chemistry data to be less protective when evaluating risk.	Acceptable.